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Ignoring Information Quality

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ARTICLES

IGNORING INFORMATION QUALITY

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Entry into the patent system is guarded by an examination process to screen out applications that impose undue costs on the public without commensurate benefit. To do this, patent examiners rely heavily on various pieces of information—both provided by the patent applicant and independently discovered by the examiner—to assess whether an application should be granted. This Article shows that there are few mechanisms at the U.S. Patent and Trademark Office for questioning the veracity of this information, even though it may be incorrect. Rather, patent examination often assumes that existence of information equals accuracy of information. Consequently, examiners may rely on information that is wrong and many decisions about patent grant may also be wrong.

While it is well known that patent examiners make frequent errors, the existing scholarship is almost entirely about what this Article terms "matching errors" (where examiners do not find information that actually exists), when "digging errors" (where examiners find information but the information is wrong) may in fact be more common. Digging errors have serious harms: nuisance suits, decreased incentives for research, and slowed technological development. The matching-digging framework introduced by this Article not only reveals new errors, it also makes the case that existing policy tools to address examination errors will not prevent or resolve these errors. Existing policy tools require that errors be visible to the public, which is currently true for matching errors but is not for digging errors. Solutions to digging errors should therefore be information forcing to remedy this asymmetry; and this Article includes several recommendations. Further, this Article uses the matching-digging framework to reconceptualize examination as a system of quasi-registration that defers many decisions about patentability to litigation. Patents should thus not be

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given a presumption of validity and doctrines of patentability as applied in litigation should not mimic their prosecution counterparts.

INTRODUCTION

As COVID-19 spread rapidly around the world in March 2020, a biotechnology company, bioMerieux, sought regulatory approval for tests to

detect the virus.[1] Just days later, Fortress Investment Group sued bioMerieux for patent infringement and asked for an injunction.[2] The case was unusual not only because of the bad optics of enjoining a useful test during a pandemic[3] but also because the patent in suit was originally developed by Theranos,[4] a company best known for fraudulently claiming the ability to make diagnostic tests that functioned with mere microliters of blood.[5] Further, although the patent in suit was based on Theranos's fraudulent technology, it covered bioMerieux's working diagnostic tests.[6] Fortress should not have sought to enjoin diagnostic tests during a pandemic—and the patent providing the basis for that suit should never have been granted.

This Article explains why the Theranos patent was granted, and predicts the existence of many similarly problematic patents, with a novel theory of examination at the U.S. Patent and Trademark Office (PTO). This Article distinguishes between "matching," the process of seeking information relevant to patentability, and "digging," the process of assessing the reliability of that information. This Article then argues that patent examiners do only the former. Put differently, examiners are good at asking whether a particular piece of evidence exists, but they do not ask whether that information is true.[7]

The process of patent examination, when viewed in light of the distinction between matching and digging, is somewhat akin to how courts assess facts on motions to dismiss. Courts search for the presence of factual allegations that match each element of a claim.[8] Courts generally accept factual allegations as true at this stage, in contrast to trial, where litigants argue vigorously about the truth of allegations.[9] As with motions to dismiss, patent examiners search for the presence of facts matching various requirements of

1. *See French Group Biomerieux Launches Three Coronavirus Tests*, REUTERS (Mar. 11, 2020), https://www.reuters.com/article/us-health-coronavirus-biomerieux/french-group-biomerieux-launches-three-coronavirus-tests-idUSKBN20Y0Z1 [https://perma.cc/58M6-BN9C].

2. Labrador Diagnostics LLC v. BioFire Diagnostics, LLC, No. 20-cv-348, 2020 WL 1283393 (D. Del. Mar. 9, 2020).

3. The optics do not reflect the full story of the case. The plaintiff explained that it was not aware that bioMerieux was working on a test for COVID-19, and it dismissed the suit upon learning of the test. Notice of Dismissal Without Prejudice at 1–2, *Labrador Diagnostics*, 2020 WL 1283393 (No. 20-cv-348).

4. U.S. Patent No. 8,283,155 (filed Oct. 8, 2009) (issued Oct. 9, 2012).

5. *E.g.*, Press Release, U.S. Dep't of Just., Theranos Founder and Former Chief Operating Officer Charged in Alleged Wire Fraud Schemes (June 15, 2018), https://www.justice.gov/usao-ndca/pr/theranos-founder-and-former-chief-operating-officer-charged-alleged-wire-fraud-schemes [https://perma.cc/5M3V-GHSU] ("[D]efendants claimed the analyzer was able to perform a full range of clinical tests using small blood samples drawn from a finger stick.").

6. '155 Patent col. 8 ll. 17–19 ("Where desired, a sample of 1 to 50 microliters or 1 to 10 microliters can be used for detecting an analyte using the subject fluidic device.").

7. *See infra* Part I.C.

8. *See* Ashcroft v. Iqbal, 556 U.S. 662, 678 (2009).

9. *See id.* Facts that are truly unlikely—such as "little green men, or the plaintiff's recent trip to Pluto, or experiences in time travel"—need not be taken as true. *Id.* at 696 (Souter, J., dissenting). This too mimics how patent examiners review facts—those that are physically impossible, such as perpetual motion machines, will not be taken as true. *See infra* Part I.C.

patentability and then accept those facts as true, without digging further into the veracity of the facts.

The distinction between matching and digging can be seen in how examiners assess the utility and novelty requirements of patentability. Inventions are only patentable if they are useful.[10] To this end, examiners must review a patent application to determine if it contains a statement of utility.[11] This is a matching task: examiners match the invention to its stated utility. If examiners find such a statement, the PTO instructs them to accept it as true, without further assessing its veracity.[12] The process of matching, but not digging into, the quality of a statement can also be seen in the novelty analysis. Inventions must be novel; they cannot be patented if an operable version of the invention has previously been publicly disclosed.[13] Examiners search the prior literature for a disclosure matching the claimed invention.[14] If examiners find a match, they reject the application.[15] The PTO instructs examiners to assume that the statement discloses a working invention; examiners do not dig into the statement to assess operability.[16]

Failure to dig into information quality leads to errors during patent examination. Examiners make decisions based on the information available to them, so if examiners cannot tell whether the information is correct—and it is clear that the information available to examiners is often *not* correct—then examiners' decisions will sometimes be wrong. When information in the patent application itself is wrong, examiners may erroneously grant a patent that is not actually useful, enabled, or adequately described (all requirements of patentability), which may then allow patentees to undeservedly monopolize an area and block future research that might lead to beneficial inventions.[17] When evidence in the prior art is wrong, examiners may erroneously reject a patent that is in fact novel and nonobvious, diminishing the patent reward and commensurate incentives to invent.[18]

There is substantial scholarship on errors that occur during patent examination, which are a major policy challenge.[19] However, this Article demonstrates that existing scholarship focuses primarily on errors caused by

10. 35 U.S.C. § 101.

11. *See* MPEP § 2107(II) (9th ed. Rev. 10, June 2020).

12. *Id.* ("Office personnel are reminded that they must treat as true a statement of fact made by an applicant in relation to an asserted utility . . . .").

13. 35 U.S.C. § 102; *see* Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Rsch., 346 F.3d 1051, 1054 (Fed. Cir. 2003).

14. *See* MPEP § 904. Examiners are not restricted to written literature. *Id.*

15. *Id.*

16. *Id.* § 2121 ("[T]he reference is presumed to be operable."); *see also In re* Antor Media Corp., 689 F.3d 1282, 1289 (Fed. Cir. 2012) ("[A]n examiner is entitled to reject claims as anticipated by a prior art publication or patent without conducting an inquiry into whether or not that prior art reference is enabling.").

17. *See infra* Part II.C.2.

18. *See infra* Part II.C.1.

19. *See infra* Part III.

failure to *find* information—matching errors.[20] Little scholarship concerns errors caused by failure to *evaluate* information—digging errors. This Article predicts that digging errors will be common because the process of examination fails entirely to screen for information quality.[21]

This Article then turns to mechanisms to prevent or fix examination errors. At the outset, existing policies targeted at fixing errors will be ineffective to address digging errors because these policies rely on the public to find errors.[22] But errors in evaluating information, unlike errors in finding information, may be invisible to the public. For example, if a patent states that an invention works, the public does not have access to the evidence underlying that statement and therefore cannot easily disagree.[23] Further, errors caused by failure to dig into the quality of information are difficult to prevent at the examination stage because examiners simply do not have the expertise, capability, funding, facilities, or time to comprehensively assess information quality.[24] This Article proposes a variety of solutions that (1) encourage information gathering and (2) place the burden of fact-checking more heavily on the parties involved in submitting the application.[25]

The matching-digging dichotomy also implicates the relationship between prosecution and litigation, both in terms of how this interface is theorized and for concrete policy proposals. Prosecution is currently viewed as an examination system, with litigation as a backstop to review errors.[26] But prosecution is actually a registration system where examiners check to ensure that an application contains all required components but where they do not dig into the accuracy of these components. Litigation, by contrast, is an examination proceeding where courts can and do assess the quality of evidence. Many aspects of patentability traditionally thought to be assessed during prosecution are thus in reality postponed for evaluation in litigation. The matching-digging dichotomy suggests that courts should give patents a presumption of *matching* (i.e., that the examiner searched for matching evidence) but that there is no basis for a presumption of *digging* (i.e., that matching evidence found by the examiner is correct).

Additionally, prosecution and litigation doctrines should be decoupled. Under current law, litigants can argue that a granted patent is invalid and courts will review validity using many of the same doctrines that apply in

20. Matching errors occur when an examiner (erroneously) fails to find a statement matching the patent's claims in the prior art, resulting in the grant of a patent that either is not novel or is obvious. *See infra* Part III.

21. *See infra* Part II.B.

22. *See infra* Part III.A.1.c.

23. *See infra* Part III.A.1.

24. *See infra* Part III.A.

25. *See infra* Part III.A.2.

26. *See* Robert P. Merges, *As Many as Six Impossible Patents Before Breakfast: Property Rights for Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577, 592 (1999).

prosecution.[27] However, if litigation involves a fundamentally different analysis, courts should not be constrained by doctrines developed by the PTO. This Article explains that several of patent law's more perplexing doctrines can be understood as shortcuts to transform digging tasks—which are beyond the capabilities of patent examiners—into matching tasks, which are more readily accomplished.[28] Because these doctrines are concessions to a weakness of examination that has no parallel in litigation, the doctrines should not apply in litigation.

A final payoff of the matching-digging dichotomy is to highlight that most of examiners' workload—matching tasks—consists of the type of job that can be done using artificial intelligence.[29] Increasing the use of artificial intelligence might therefore free an examiner's time to perform more difficult tasks, such as digging into the quality of evidence.

Part I provides background on the patent examination process. It then sets out the matching-digging divide by explaining how examiners match but do not dig into the quality of information. Part II models different types of patent errors under the matching-digging framework and shows that certain types of errors will be common results of failure to dig into information. Part III turns to implications and policy reform, beginning with suggestions for fixing digging errors, followed by reforms for litigation, and concluding with a discussion of the potential for automating patent prosecution.

I. INFORMATION AND PATENT EXAMINATION

A. Background on Examination

The purpose of patent examination is to screen out applications that do not meet the requirements of patentability. Patents impose a burden on the public in the form of higher prices during the term of the patent, so they should only be granted if they provide a public benefit by disclosing new and useful technologies. This quid pro quo—patentees gets the exclusive right to their inventions in return for providing knowledge to the public—is designed to incentivize innovation. It gives patentees an opportunity to profit from their inventions and also adds to the public repository of knowledge.

Each patent undergoes examination at the PTO to ensure that it meets the requirements for patentability. The invention, which is defined by a portion of the patent called the "claims,"[30] must be novel[31] and nonobvious,[32] meaning that it has never been previously publicly disclosed, nor is it an obvious variation of something previously disclosed.[33] To assess novelty

27. *See, e.g.*, 35 U.S.C. § 282(b)(2). Note that some doctrines differ between prosecution and litigation, notably claims are given their broadest reasonable interpretation during prosecution. MPEP § 2111 (9th ed. Rev. 10, June 2020).

28. *See infra* Part III.B.2.

29. *See infra* Part III.C.

30. 37 C.F.R. § 1.75(a) (2020).

31. 35 U.S.C. § 102.

32. *Id.* § 103.

33. KSR Int'l Co. v. Teleflex Inc., 550 U.S. 398, 400 (2007).

and nonobviousness, examiners search the "prior art" (the universe of public disclosures made before the patent was filed) to determine if the invention or related concepts were already known.[34]

The invention must also be useful,[35] enabled (disclosed in sufficient detail such that other scientists can make and use the invention),[36] and adequately described.[37] These requirements pertain to information in the patent application itself, called the "specification."[38] Examiners will check the specification to ensure that it describes the invention (as defined in the claims), contains a statement of utility, and includes specifics about how to make and use the invention.[39] This ensures both that the patent goes to an inventor who has developed the invention to a stage where it is useful and that the patent discloses enough information that other scientists can develop improvements and downstream iterations of the technology.

Finally, the invention must also meet certain other requirements, such as relating to subject matter that can be patented[40] and including claims that clearly outline the boundaries of the patent.[41]

B. Matching

This Article argues that evidentiary analysis, such as that done in patent examination, can be understood as a process consisting of two steps: matching and digging. Part II.B defines matching and explores how matching is used to assess patentability. Part II.C argues that while the *existence* of certain pieces of information is a vital component of the examination process, the *accuracy* of that information is not—examiners do not dig into information quality.

Matching is defined as selecting a statement and searching for a similar statement documented elsewhere. For example, I propose that "the sky is blue." This statement matches to many other statements in other sources, including a short article by NASA explaining why the sky is blue.[42] In the context of patent examination, matching involves taking the claimed invention and asking whether evidence of the claimed invention exists elsewhere.

34. Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 22 (1966).
35. 35 U.S.C. § 101.
36. *Id.* § 112(a).
37. *Id.*
38. *Id.*
39. *See, e.g.*, *In re* Brana, 51 F.3d 1560, 1562–63 (Fed. Cir. 1995).
40. 35 U.S.C. § 101.
41. *See id.* § 112(b).
42. *Why Is the Sky Blue?*, NASA SCI. SPACEPLACE (Apr. 21, 2020), https://spaceplace.nasa.gov/blue-sky/en/ [https://perma.cc/R5aJK-J5WZ].

Table 1: Summary of Matching During Assessment of Patentability

Patentability Requirement	Area Searched for Matching Information	Consequence of Finding Matching Information
Novelty	Prior Art	Not Patentable
Obviousness	Prior Art	Not Patentable
Enablement	Specification	Patentable
Written Description	Specification	Patentable
Utility	Specification	Patentable

Patents are only granted on inventions that are novel and nonobvious: that have not been previously publicly disclosed and are not obvious based on the sum of existing knowledge.[43] When a patent application is submitted, examiners must therefore determine if the invention has been previously disclosed in a publicly available source—the prior art—or whether it would be obvious over such disclosures.[44] Examiners do this by searching the prior art for disclosures that match the claimed invention.[45] An application will be rejected for lack of novelty if a piece of prior art matches all aspects of the claimed invention.[46] An application will be rejected for obviousness if each part of the invention matches some disclosure in the prior art and it would be obvious to combine those disclosures.[47]

For example, an applicant claimed to have invented a process for rendering fruit rind resistant to mold by "subjecting fruit to the action of an aqueous solution of borax."[48] In order to determine if the invention was patentable, the examiner had to search for a matching statement in prior published documents. The examiner found a match: a document published several years earlier describing a method "to prolong the period of usefulness of

43. 35 U.S.C. §§ 102–103; MPEP § 2131 (9th ed. Rev. 10, June 2020) ("A claimed invention may be rejected under 35 U.S.C. § 102 when the invention is anticipated (or is 'not novel') over a disclosure that is available as prior art."). Patents impose a cost on society by allowing the patentee to charge higher prices for a product. In return, patents disclose information about technology that might otherwise be kept secret. Thus, patents are only granted on technology that has not been previously disclosed, because otherwise the cost would not be worth the benefit. *See, e.g.*, Suzanne Scotchmer & Jerry Green, *Novelty and Disclosure in Patent Law*, 21 RAND J. ECON. 131, 132 (1990).

44. MPEP § 901.

45. *Id.*

46. *Id.* § 2131.

47. *Id.* § 2141.

48. Am. Fruit Growers v. Brogdex Co., 283 U.S. 1, 6 (1931).

fruit . . . . [consisting of] [t]he application of boracic acid."[49] The application was therefore deemed not novel and was rejected. The examiner evaluated the patentability of the invention by matching the claims of the patent application to statements in the prior art.

Examiners also use matching techniques to evaluate the enablement requirement. Enablement requires that patents provide sufficient information about the invention so that it can be made and used by others in the field without undue experimentation.[50] To assess whether this is the case, examiners take each element of the claimed invention and seek to match it to a description in the patent's specification of how the element is made and used.[51] If one or more steps is missing from the patent's description, the examiner will reject the patent for lack of enablement.[52] This is a matching technique. Examiners take statements from the claims and seek matching explanations for that information in the patent.

For example, a patent claim was directed to using x-rays to differentiate types of plastics, a process which, among other things, required "selecting for processing" the x-ray signals that did not pass through the plastics.[53] The patent specification did not explain how to select those signals—in other words, the specification did not contain a match for a necessary step in the claim—therefore, the patent was not enabled.[54]

Matching also occurs when examiners evaluate the written description requirement. Written description requires that patents contain enough information to show that the inventors were "in possession" of the claimed invention.[55] This is presumed to be the case if "the claimed invention is present in the specification."[56] Determining if the claimed invention is in the specification is a matching task. For each element of the claimed invention, the examiner checks to see if matching information is present in the specification. If there is no match for a part of the claimed invention, the examiner can reject the patent.[57] For example, a patent claiming a method of conducting debit card transactions using multiple authorization codes did not have an explanation in the specification that included multiple authorization codes and thus, was rejected for lack of written description.[58]

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49. *Id.* at 13. Note that in this case, boracic acid was sufficiently similar to borax, such that it anticipated the applicant's invention.

50. 35 U.S.C. § 112; *In re* Wands, 858 F.2d 731, 733 (Fed. Cir. 1988). The purpose of enablement is to ensure that information about new inventions is disseminated to the public so that others can recreate and improve on the technology. Janet Freilich, *The Replicability Crisis in Patent Law*, 95 IND. L.J. 431, 438 (2020).

51. *See* MPEP § 2164.06(a).

52. *Id.* ("It is common that doubt arises about enablement because information is missing about one or more essential claim elements.").

53. Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc., 166 F.3d 1190, 1195 (Fed. Cir. 1999).

54. *See id.* at 1196.

55. Capon v. Eshhar, 418 F.3d 1349, 1357 (Fed. Cir. 2005).

56. *In re* Wertheim, 541 F.2d 257, 262 (C.C.P.A. 1976); *see also* MPEP § 2163(II)(A).

57. *See, e.g.*, MPEP § 2163(II)(A).

58. Stored Value Sols., Inc. v. Card Activation Techs., Inc., 499 F. App'x 5, 13–14 (Fed. Cir. 2012).

Because the specification had no match for the "multiple authorization codes" portion of the claim, the patent was not valid.[59]

Finally, examiners use matching to assess the utility requirement for patentability. Inventions can only be patented if they are useful.[60] Inventions are not useful if they have no purpose or are impossible. Patents should include a statement about the utility of the invention: an explanation for how the invention can be used.[61] When examining a patent for utility, the examiner matches the claimed invention to the statement of utility in the specification.[62] For example, a patent application claimed a particular compound and, in the specification, stated that the compound was useful as a plant fungicide.[63] Because there was a match between the claimed compound and the disclosed utility, the application satisfied the utility requirement.[64]

C. Digging

As shown above, patent examiners search for information matching the claimed invention in both the prior art and in the patent application itself. This part argues that patent examiners do not dig into the quality of the information they find. Although examiners look for evidence of patentability both in the prior art and the patent specification, they do not assess whether that evidence is correct.

The strongest indication that examiners are not digging into the quality of evidence comes from the PTO's own admission. The PTO straightforwardly confesses that it does not and cannot determine whether certain types of information are correct. For example, the examiner in *Ex Parte Baker*[65] cited a statement in the prior art that a particular antibody could bind to a protein—

59. *Id.* Examiners also use matching to determine if applicants can amend the claims of their applications. Amendments cannot introduce new matter into the claims—doing so violates the written description requirement. *See* Chiron Corp. v. Genentech, Inc., 363 F.3d 1247, 1255 (Fed. Cir. 2004) ("The written description requirement prevents applicants from using the amendment process to update their disclosures . . . ."). Thus, to determine if an amendment adds material that is not in the originally filed application, the examiner matches the material added in the amendment to material already in the specification. MPEP § 2163(II)(B).

60. 35 U.S.C. § 101. As with novelty and nonobviousness, society should not bear the cost of a patent if the disclosed invention has no use or if the inventor does not or cannot describe the use. *See, e.g.*, Brenner v. Manson, 383 U.S. 519, 534 (1966) ("Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly . . . . may engross a vast, unknown, and perhaps unknowable area. Such a patent may confer power to block off whole areas of scientific development, without compensating benefit to the public.").

61. MPEP § 2107.02(II)(A). Patents must have a statement to "fully and clearly explain why the applicant believes the invention is useful. Such statements will usually explain the purpose of or how the invention may be used . . . ." *Id.*

62. The PTO instructs examiners to "(A) Read the claims and . . . . [d]etermine what the applicant has claimed" and "(B) . . . determine if the applicant has asserted for the claimed invention any specific and substantial utility that is credible." *Id.* § 2107 (II).

63. *In re* Gottlieb, 328 F.2d 1016, 1019 (C.C.P.A. 1964).

64. *Id.*

65. No. 2006-2892, 2007 WL 630236 (B.P.A.I. Feb. 26, 2007).

but the PTO also acknowledged that it could not check whether that statement was true, explaining that "the Office does not have the facilities for examining and comparing Appellant's protein/antibody."[66] In *Ex Parte Reguri*,[67] the applicants claimed a particular form of valsartan, a drug that treats hypertension.[68] Prior art had disclosed a similar form, but the applicant contended that it was not a true match because, if the examiner were to test the prior art composition, it would be clear that the prior art disclosed a slightly different form of valsartan.[69] The Board of Patent Appeals and Interferences rejected the applicant's argument and explained that the examiner could not verify which type of valsartan was disclosed by the prior art because the "Office does not have the facilities to determine what form or admixtures of forms" the prior art compound takes.[70]

Courts agree with the PTO's explanation that it is unable to dig into the quality of evidence. In *Corning Glass Works v. Anchor Hocking Glass Corp.*,[71] the applicant made certain misrepresentations to the PTO.[72] The court explained that dishonesty in PTO proceedings was a particular problem because "an examiner has no way, in many cases, to ascertain the truthfulness of the representations made to him."[73] In *Charles Pfizer & Co. v. FTC*,[74] Pfizer presented misleading information to the examiner.[75] The court remarked that this misleading information caused the examiner to erroneously grant the patent because the "Patent Office, not having testing facilities of its own, must rely upon information furnished by applicants."[76]

These passages demonstrate that the PTO lacks the ability to evaluate the veracity of evidence in certain scenarios and instead merely assumes that relevant information is true. However, failure to evaluate evidence is considerably more widespread, and it permeates every aspect of examiner behavior. The sections below survey PTO rules and practices to investigate how examiners assess evidence.

1. Treatment of Prior Art References

Examiners fail to evaluate the quality of evidence in prior art documents used to reject an application. This occurs because legal doctrine allows examiners to assume that information in prior art is accurate—obviating the need to dig—even though there is ample reason to believe that much information in prior art is *not* accurate.

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66. *Id.* at *3.
67. No. 2007-0313, 2007 WL 2745815 (B.P.A.I. Sept. 6, 2007).
68. *Id.* at *2.
69. *Id.*
70. *Id.* at *7.
71. 253 F. Supp. 461 (D. Del. 1966), *aff'd in part, rev'd in part*, 374 F.2d 473 (3d Cir. 1967).
72. *Id.* at 470.
73. *Id.*
74. 401 F.2d 574 (6th Cir. 1968).
75. *Id.* at 579.
76. *Id.*

When an examiner rejects a patent for lack of novelty or for obviousness, she will cite to specific prior art references that either anticipated or rendered the invention obvious.[77] This citation indicates that the examiner has searched the prior art and found a reference that matches the claimed invention.[78] According to patent doctrine, a reference used for an anticipation rejection must be enabled, meaning that the invention disclosed in the prior art must be operable or could be operable without undue experimentation.[79] The rationale for this requirement is that inventors should not get patents on inventions that are already in the possession of the public.[80] Further, in order for the public to possess an invention, the prior art must do more than just disclose an idea—the prior art must teach the public how to make a working version of the invention.[81]

However, in practice, the examiner need only find prior art that discloses the applicant's invention and need not ask whether the reference discloses something that actually works.[82] The PTO instructs examiners that, if the reference is used for an anticipation or obviousness rejection, "the reference is presumed to be operable."[83] This means that examiners must find a disclosure of the invention in the prior art but can then assume that the statements are accurate and need not dig into their quality.

The Federal Circuit has confirmed that "an examiner is entitled to reject claims as anticipated by a prior art publication . . . without conducting an inquiry into whether or not that prior art reference is enabling."[84] The Federal Circuit explained that the examiner is not required to investigate whether the prior art works because "[i]t would be overly cumbersome, perhaps even impossible, to impose on the PTO the burden of showing that a cited piece of prior art is enabling. The PTO does not have laboratories for testing disclosures for enablement."[85] Thus, as long as examiners have found the applicant's invention disclosed in the prior art, they need not ask whether the prior art is accurate—and indeed, examiners generally *could not* dig into the prior art's accuracy.

77. MPEP §§ 2131, 2143 (9th ed. Rev. 10, June 2020).

78. *See infra* Part III.A.

79. Elan Pharms., Inc. v. Mayo Found. for Med. Educ. & Rsch., 346 F.3d 1051, 1054 (Fed. Cir. 2003); *In re* Donohue, 766 F.2d 531, 533 (Fed. Cir. 1985).

80. *See* Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 148 (1989) (explaining that the novelty requirement "express[es] a congressional determination that the creation of a monopoly in [publicly disclosed] information would . . . serve no socially useful purpose").

81. *In re Donohue*, 766 F.2d at 533 (Fed. Cir. 1985) (stating that prior art must "sufficiently describe the claimed invention to have placed the public in possession of it" and that, as part of this requirement, the description must be enabling).

82. Amgen Inc. v. Hoechst Marion Roussel Inc., 314 F.3d 1313, 1354 (Fed. Cir. 2003); *In re* Sasse, 629 F.2d 675, 677 (C.C.P.A. 1988).

83. MPEP § 2121(I) (9th ed. Rev. 10, June 2020).

84. *In re* Antor Media Corp., 689 F.3d 1282, 1289 (Fed. Cir. 2012).

85. *Id.* at 1288.

With respect to obviousness, there is no requirement that the prior art be enabled.[86] A patent application can be rejected on the grounds that it is obvious over prior art even if the author of the prior art did not know how to make the invention.[87] Thus, the examiner is free of even a nominal burden to determine if the prior art disclosure is correct.

Further evidence that examiners do not dig into the quality of information used during the novelty and nonobviousness analyses comes from the types of sources used by examiners. Examiners almost always cite to patents, rather than to journal articles or other types of disclosures, as prior art.[88] Patents have no indicators to distinguish good quality patents from poor quality patents, unlike journal articles, where the journal of publication might so indicate. Thus, the prior art used most often by examiners lacks indicators that could be used to evaluate its informational value.

Moreover, examiners are more likely to cite to abandoned patent applications than to granted patents.[89] Abandoned patent applications may never have been reviewed by a patent examiner, so the quality of the statements therein is essentially the same as a self-published piece of writing.[90] This practice is explicitly permitted by the PTO, which instructs examiners to give prior art patents the same evidentiary weight as prior art patent applications.[91]

Examiners fail to consider the quality of statements in prior art even when it should be clear that the prior art is blatantly incorrect. As discussed above, Theranos filed a patent on a method of measuring analytes in small drops of blood.[92] An examiner cited the Theranos patent as prior art to reject as obvious a downstream patent claiming a method of measuring analytes in small drops of sweat.[93] The rejection occurred in 2019, long after Theranos's inability to make their technology functional had been well publicized.[94] Yet the examiner argued that it was obvious how to measure molecules in small

86. Metso Mins., Inc. v. Powerscreen Int'l Distrib. Ltd., 526 F. App'x 988, 994–95 (Fed. Cir. 2013); Geo M. Martin Co. v. All. Mach. Sys. Int'l LLC, 618 F.3d 1294, 1302–03 (Fed. Cir. 2010).

87. *Geo M. Martin*, 619 F.3d at 1303.

88. Colleen Chien, *Comparative Patent Quality*, 50 ARIZ. ST. L.J. 71, 121–22 (2018).

89. Christopher A. Cotropia & David L. Schwartz, *The Hidden Value of Abandoned Applications to the Patent System*, 61 B.C. L. REV. 2809, 2810 (2020). Applications are deemed abandoned if the applicant stops pursuing the application. *Id.* at 2811 n.3.

90. The quality is perhaps slightly higher, since filing a patent costs several hundred dollars and therefore may dissuade at least some poorly researched ideas. *See* Jonathan S. Masur, *Costly Screens and Patent Examination*, 2 J. LEGAL ANALYSIS 687, 687 (2008) (explaining that the high cost of patent review may screen out low value patents).

91. MPEP § 2121(II) (9th ed. Rev. 10, June 2020) ("The level of disclosure required within a reference to make it an 'enabling disclosure' is the same no matter what type of prior art is at issue. It does not matter whether the prior art reference is a U.S. patent, foreign patent, a printed publication [a patent application] or other.").

92. U.S. Patent No. 10,156,579 col. 24 l. 7 (filed Feb. 26, 2016) (issued Dec. 18, 2018) ("A method of detecting an analyte in a small-volume blood sample obtained from a subject, comprising: a) obtaining a sample of blood from a subject by lancing or pipetting, said blood sample having a volume of less than about 500 μL.").

93. WIPO Patent Application No. 2018/013579 (filed July 11, 2017).

94. *Id.*

drops of liquid because Theranos had already done it.[95] This nonsensical approach shows that the examiner was matching (finding a reference that disclosed the technique) without digging (evaluating the reliability of that reference).

2. Utility

A second demonstration that patent examiners are not assessing the quality of evidence used to evaluate patentability comes from the PTO's instructions to examiners on how to assess whether a patent application is useful. As explained above, patent examiners assess utility by finding a statement in the patent document that explains how the invention can be used.[96] However, after finding such a statement, examiners generally accept it at face value and do not attempt to assess its reliability.

Patent examiners are not required to accept the applicant's assertion that the invention is useful as true.[97] But the PTO emphasizes that rejections on the grounds that the examiner doubts the veracity of the applicant's statement are "rare" and instances of such rejections being upheld by a federal court "even rarer."[98] Further, although examiners are permitted to request that the applicant provide additional evidence of utility if the examiner is not satisfied with the initial statement, such requests for additional evidence "should be imposed rarely."[99] The PTO allows examiners to dispute an applicant's stated utility only where the assertion is "incredible in view of contemporary knowledge" and not merely where "there may be reason to believe that the assertion is not entirely accurate."[100] Indeed, the PTO explains that examiners reject applications for lack of credible utility mainly when the claimed invention "violate[s] a scientific principle, such as the second law of thermodynamics."[101] Patents on perpetual motion machines, which are physically impossible, are filed with surprising regularity.[102]

To paraphrase, the PTO instructs examiners to accept the applicant's stated utility unless it is utterly impossible. The expectation appears to be that, with respect to evidence of utility, examiners search for information about utility but do not dig into the quality of the information.

3. Enablement and Written Description

To determine if a patent is enabled, examiners must ask whether there is sufficient evidence in the patent document to teach others in the field how to

95. *Id.*
96. *See supra* Part II.B.
97. *E.g.*, MPEP § 2107(II) (9th ed. Rev. 10, June 2020) (describing rejections where an examiner challenged the applicant's asserted utility on the basis that the applicant's statement was "incredible in the light of the knowledge of the art").
98. *Id.* § 2107.01(II).
99. *Id.* § 2107.02(V).
100. *Id.* § 2107.02 (III)(B).
101. *Id.*
102. *Id.*

make and use the invention.[103] The written description requirement calls for a similar assessment of evidence in the patent document to ensure that the inventor is in possession of the claimed invention.[104] As discussed previously, examiners do this by asking whether relevant information is present in the patent document.[105] This section explains that once the examiner finds such information, she does not inquire further into its quality unless the information is plainly unbelievable.

As an initial assessment of whether examiners dig into information quality, I reviewed one hundred randomly selected enablement and written description rejections[106] where the examiner asserted that at least one claim of a patent application was not enabled and/or adequately described.[107] I asked whether the examiner rejected the application on the grounds that (1) he could not *find* relevant information or (2) that she found relevant information but the information was not *accurate*. In all one hundred rejections, the examiner rejected the application on the first ground: that some piece of necessary information could not be found.[108] In none of the rejections did the examiner state that relevant information was present but that the information was unreliable. This is threshold evidence that examiners seek the presence of information but do not evaluate its accuracy.

Of course, if all information found by examiners were plainly correct, examiners would not need to discuss its accuracy. However, that is not the case. In many instances, examiners accepted evidence that was so unclear that its accuracy could not possibly have been evaluated. For instance, an important source of evidence in patents is visual evidence (drawings), but this evidence can be of such poor quality that it is impossible that the examiner could have understood the drawings. The images below, for example, are part of the inventors' efforts to enable and describe the inventions. However, because the drawings are utterly incomprehensible (the viewer is supposed to see a white arrow pointing at something visible,

103. 35 U.S.C. § 112(a).

104. *Id.*

105. And how to combine it with other elements. *See supra* Part I.B.

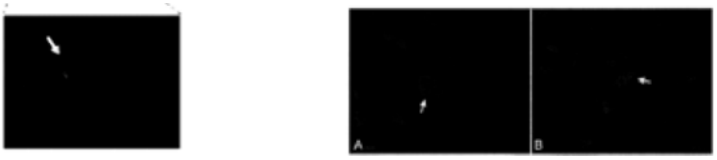
106. These were selected from the Office Action Research Dataset for Patents. *See generally* U.S. PAT. & TRADEMARK OFF., *Office Action Research Dataset for Patents*, https://www.uspto.gov/learning-and-resources/electronic-data-products/office-action-research-dataset-patents [https://perma.cc/J9FL-JC43] (last visited Mar. 16, 2021). For more information on this dataset, see Qiang Lu et al., *USPTO Patent Prosecution Research Data: Unlocking Office Action Traits* (USPTO Econ. Working Paper No. 2017-10, 2017), https://ssrn.com/abstract=3024621 [https://perma.cc/E36V-XLQD].

107. Applications are often rejected for both lack of enablement and written description. Lu et al., *supra* note 106, at 2.

108. The following example illustrates a rejection made because the examiner could not find some piece of information relevant to enablement. A patent, filed by DaimlerChrysler, claims an improved windshield wiper blade with "two projections extending laterally from first end of" the bow of the blade. U.S. Patent Application No. 11/085,332 para. 7 (filed Mar. 21, 2005) (issued Sept. 21, 2006). The examiner rejected the application for lack of enablement because "there does not appear to be any disclosure of . . . projections . . . extending laterally . . . ." Non-Final Rejection 5 (U.S. Patent Application No. 11/085,332) (filed Mar. 21, 2006). The examiner made the rejection because he did not find a match in the specification for the wiper blade described in the claim.

not a black square), the images clearly do not teach others how to make and use the invention, nor do they prove that the inventor was in possession of the invention.[109] Yet, the examiners did not mention that the drawings do not show what the description purports them to show.[110]

Figure 1: Inventor Drawings[111]



Examiners receiving patents with poor quality images are permitted to ask the applicants to revise the images.[112] The Manual of Patent Examining Procedure specifically states that photographs (like those above) "must be of sufficient quality so that all details in the photographs are reproducible in the printed patent."[113] That examiners do not request clearer images suggests that examiners are simply checking the boxes when it comes to enablement—looking for a statement of enablement and written description (the patentee's explanation of the image) but ignoring whether the statement is supported by evidence (the image itself). For instance, the examiner in the application above must have accepted that "[m]etaphase chromosomes . . . are apparent in small dividing cardiomyocytes"[114] on the strength of the statement alone because it is impossible to verify the statement by looking at the image.

Examiners not only accept evidence that is incomprehensible, but they also accept evidence that is clearly wrong. For example, U.S. Patent No. 8,647,872 claims a method of producing embryonic stem cells and supports this claim by providing a detailed explanation of how the stem cells can be prepared.[115] Unfortunately, the technique does not work: a paper by the inventors in *Science* was retracted after a highly publicized scandal; the lead inventor was criminally charged and admitted in court that he had forged the

109. It is not clear why the black squares are in the patent application. It is likely that they are poor quality photocopies of other images.

110. These drawings clearly contravene the PTO's requirement that "[d]rawings will be accepted . . . if the drawings are readable and reproducible for publication purposes." MPEP § 608.02(b)(I) (9th ed. Rev. 10, June 2020).

111. The image on the left is from U.S. Patent No. 9,574,173 col. 12 l. 7 (filed Nov. 5, 2011) (issued Feb. 21, 2017) ("[I]mmunofluorescence microscopic analysis indicates that the immunofluorescent GFP-tagged tNSCs still persisted in the lesioned striatum . . . ."). The images on the right are drawn from U.S. Patent Application No. 12/324,031 [27] (filed Nov. 26, 2008) ("Metaphase chromosomes (A and B: blue, PI; arrows) . . . are apparent in small dividing cardiomyocytes . . . .").

112. MPEP § 608.02(b)(I)–(II) ("Examiners should review the drawings for disclosure of the claimed invention . . . . if the original drawings are unacceptable, applicant will be notified and informed of what the objections are and that new corrected drawings are required.").

113. 37 C.F.R. § 1.84(b)(1) (2020).

114. U.S. Patent Application No. 12/324,031 [27].

115. U.S. Patent No. 8,647,872 claim 1 (filed Dec. 9, 2011) (issued Feb. 11, 2014).

data.[116] In a strange twist, the trial also revealed that he had worked with the Russian mafia to clone extinct mammoths.[117] The patent was granted more than ten years after the retraction made headlines in both the scientific and popular media, suggesting that there was ample opportunity for the PTO to learn about the retraction and reject the patent.[118] The examiner was apparently looking only for statements that described how to make and use the stem cells—statements that were present in the application—but did not dig into the reliability (or lack thereof) of those statements.[119]

II. A NEW MODEL FOR EXAMINER ERRORS

One consequence of examiners' failure to evaluate the quality of information used to assess patentability is errors. It is well known that patent examiners make frequent errors during examination. There is a large body of scholarship on these errors and there are ongoing policy efforts to reduce and resolve these errors.[120] However, existing scholarship and policy efforts focus almost exclusively on errors in *finding* information, whereas this Article predicts widespread errors in *evaluating* information.[121] As a result, there are likely a significant number of errors that are not recognized by current scholarship. While the existing consensus is that patent examiners

116. *Hwang Admits Faking Data*, SCI. (Oct. 30, 2006, 12:00 AM), https://www.sciencemag.org/news/2006/10/hwang-admits-faking-data [https://perma.cc/9WW3-VRXY].

117. *Id.*

118. *See* Andrew Pollack, *Disgraced Scientist Granted U.S. Patent for Work Found to Be Fraudulent*, N.Y. TIMES (Feb. 14, 2014), https://www.nytimes.com/2014/02/15/science/disgraced-scientist-granted-us-patent-for-work-found-to-be-fraudulent.html [https://perma.cc/W6MF-W7HK].

119. *Id.*

120. *See generally* ADAM B. JAFFE & JOSHUA LERNER, INNOVATION AND ITS DISCONTENTS: HOW OUR BROKEN PATENT SYSTEM IS ENDANGERING INNOVATION AND PROGRESS, AND WHAT TO DO ABOUT IT (2004); U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-465, INTELLECTUAL PROPERTY: ASSESSING FACTORS THAT AFFECT PATENT INFRINGEMENT LITIGATION COULD HELP IMPROVE PATENT QUALITY (2013); U.S. GOV'T ACCOUNTABILITY OFF., GAO-16-460, INTELLECTUAL PROPERTY: PATENT OFFICE SHOULD DEFINE QUALITY, REASSESS INCENTIVES, AND IMPROVE CLARITY (2016); John R. Allison & Ronald J. Mann, *The Disputed Quality of Software Patents*, 85 WASH. U. L. REV. 297 (2007); Michael D. Frakes & Melissa F. Wasserman, *Does the U.S. Patent and Trademark Office Grant Too Many Bad Patents: Evidence from a Quasi-experiment*, 67 STAN. L. REV. 613 (2015); Christi J. Guerrini, *Defining Patent Quality*, 82 FORDHAM L. REV. 3091 (2014); Mark A. Lemley & Bhaven Sampat, *Examining Patent Examination*, 2010 STAN. TECH. L. REV. 2; R. Polk Wagner, *Understanding Patent-Quality Mechanisms*, 157 U. PA. L. REV. 2135 (2009); Stephen Yelderman, *Improving Patent Quality with Applicant Incentives*, 28 HARV. J.L. & TECH. 77 (2014); Gaetan de Rassenfosse et al., *Low-Quality Patents in the Eye of the Beholder: Evidence from Multiple Examiners* (Nat'l Bureau of Econ. Rsch., Working Paper No. 22244, 2019), https://www.nber.org/system/files/working_papers/w22244/w22244.pdf [https://perma.cc/9W9M-RDYF].

121. Some scholars have written about errors caused by incorrect information, but this literature is substantially smaller than the literature on matching errors. *See, e.g.*, Janet Freilich & Lisa Larrimore Ouellette, *Science Fiction: Fictitious Experiments in Patents*, 364 SCI. 1036, 1036 (2019); Freilich, *supra* note 50, at 10; Lisa Larrimore Ouellette, Pierson*, Peer Review, and Patent Law*, 69 VAND. L. REV. 1825, 1827 (2016); Sean B. Seymore, *Making Patents Useful*, 98 MINN. L. REV. 1046, 1092 (2014).

make a substantial number of errors, the true scope of the problem is likely considerably worse.

This part begins by showing that current scholarship has focused on matching errors (failure to find information) and then explores the likely prevalence and consequences of digging errors (failure to evaluate information).

A. Matching Errors

Almost all scholarship on patent errors and poor quality patents has focused on patents that are erroneously granted even though they are not novel or are obvious.[122] These errors are caused by failure to find matching information. When patent examiners assess whether the invention claimed in a patent application is novel or nonobvious, they search for prior public disclosures matching the invention. Because the universe of prior public disclosures is exceedingly large[123] and patent examiners have little time to process each application,[124] they often overlook relevant prior art and grant a patent on an invention even though that invention has previously been disclosed.[125]

Scholars studying these erroneously granted patents have identified the many problems that the errors cause for the patent system. Erroneously granted patents are often used as the basis for demand letters, nuisance

122. *See, e.g.*, John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 208 (1998); Robert D. Atkinson & Daniel D. Castro, *A National Technology Agenda for the New Administration*, 11 YALE J.L. & TECH. 190, 193 (2009); Joseph Farrell & Robert P. Merges, *Incentives to Challenge and Defend Patents: Why Litigation Won't Reliably Fix Patent Office Errors and Why Administrative Patent Review Might Help*, 19 BERKELEY TECH. L.J. 943, 944–46 (2004); Roger Allan Ford, *Patent Invalidity Versus Noninfringement*, 99 CORNELL L. REV. 71, 73 (2013); Michael D. Frakes & Melissa F. Wasserman, *Does Agency Funding Affect Decisionmaking: An Empirical Assessment of the PTO's Granting Patterns*, 66 VAND. L. REV. 67, 71 (2013); Mark A. Lemley, *Ignoring Patents*, 2008 MICH. ST. L. REV. 19, 20; Mark A. Lemley & Bhaven Sampat, *Is the Patent Office a Rubber Stamp?*, 58 EMORY L.J. 181, 185 (2008); Doug Lichtman & Mark A. Lemley, *Rethinking Patent Law's Presumption of Validity*, 60 STAN. L. REV. 45, 47 (2007); Merges, *supra* note 26, at 589; Michael J. Meurer, *Controlling Opportunistic and Anti-competitive Intellectual Property Litigation*, 44 B.C. L. REV. 509, 541 (2003); Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control*, 157 U. PA. L. REV. 2051, 2080 (2009); David Schumann, *Obviousness with Business Methods*, 56 U. MIA. L. REV. 727, 764 (2002); Wagner, *supra* note 120, at 2139. *See generally* JAMES BESSEN & MICHAEL J. MEURER, PATENT FAILURE: HOW JUDGES, BUREAUCRATS, AND LAWYERS PUT INNOVATORS AT RISK (2009); DAN L. BURK & MARK A. LEMLEY, THE PATENT CRISIS AND HOW THE COURTS CAN SOLVE IT (2008); JAFFE & LERNER, *supra* note 120.

123. These disclosures may be in any language and originate in any country. A disclosure may be considered public even it is relatively obscure. For example, one Federal Circuit case famously held that a patent application was not novel because the invention had been previously disclosed in a PhD thesis that existed in one copy in a German library and may not have been catalogued at the time the patent was filed. *In re* Hall, 781 F.2d 897, 898 (Fed. Cir. 1986).

124. Patent examiners have approximately eighteen hours for each application. Mark A. Lemley, *Rational Ignorance at the Patent Office*, 95 NW. U. L. REV. 1495, 1500 (2001).

125. BESSEN & MEURER, *supra* note 122, at 247.

litigation, and extortion by patent trolls.[126] Further, an abundance of patents, even if invalid, clutters the patent record and complicates freedom-to-operate searches,[127] which can chill downstream research. If later innovators see that there are hundreds of patents covering a field, they may believe that it would be too difficult to license patents in that field and therefore pick a different area of research, even if many of the patents are of dubious validity.[128] Erroneously granted patents are a substantial and important problem in patent law and have been the subject of many recent policy changes,[129] proposals,[130] and initiatives, most recently a Senate Committee on the Judiciary hearing entitled "How Can Congress Prevent the Issuance of Poor Quality Patents?"[131]

B. Digging Errors

Patent examiners can also make errors by failing to dig into the information used to make decisions about patentability. As a threshold matter, an examiner's failure to inquire into the quality of evidence will only lead to errors if the evidence reviewed by patent examiners is sometimes incorrect. Part II.B.1 provides evidence that examiners indeed often consider incorrect information. Part II.B.2 explores the consequences of errors that occur when an examiner believes that information is right but the information

126. *See, e.g.*, John R. Allison et al., *Patent Quality and Settlement Among Repeat Patent Litigants*, 99 GEO. L.J. 677, 678 (2011); Colleen Chien, *Startups and Patent Trolls*, 17 STAN. TECH. L. REV. 461, 466 (2014); Lauren Cohen et al., *Patent Trolls: Evidence from Targeted Firms*, 65 MGMT. SCI. 5461, 5461 (2019); Mark D. Janis, *Reforming Patent Validity Litigation: The "Dubious Preponderance,"* 19 BERKELEY TECH. L.J. 923, 941 (2004). Because patent litigation is expensive and unpredictable, recipients of demand letters may be willing to pay a substantial sum to avoid litigation even if they believe a patent is invalid.

127. *See* FED. TRADE COMM'N, THE EVOLVING IP MARKETPLACE: ALIGNING PATENT NOTICE AND REMEDIES WITH COMPETITION 116 (2011), https://www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf [https://perma.cc/2D3A-A4DY]; *see also* Ian Ayres & Gideon Parchomovsky, *Tradeable Patent Rights*, 60 STAN. L. REV. 863, 867 (2007); Iain M. Cockburn et al., *Patent Thickets, Licensing and Innovative Performance*, 19 INDUS. & CORP. CHANGE 899, 905 (2010); Alberto Galasso & Mark Schankerman, *Patent Thickets, Courts, and the Market for Innovation*, 41 RAND J. ECON. 472, 472 (2010).

128. James Bessen & Michael J. Meurer, *Lessons for Patent Policy from Empirical Research on Patent Litigation*, 9 LEWIS & CLARK L. REV. 1, 16 (2005); Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation?: The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998); Mark A. Lemley & Carl Shapiro, *Patent Holdup and Royalty Stacking*, 85 TEX. L. REV. 1991, 1993 (2007). *But see* Lemley, *supra* note 122, at 21 (suggesting that poor quality patents are generally ignored).

129. Reforms included in the Leahy-Smith America Invents Act, Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified as amended in scattered sections of the U.S.C.), were intended to "weed out . . . low quality patents." H.R. REP. NO. 112-98, at 38–40 (2011); Paul R. Gugliuzza, *IP Injury and the Institutions of Patent Law*, 98 IOWA L. REV. 747, 748–49 (2013).

130. *See, e.g.*, Patent Quality Improvement Act, S. 866, 113th Cong. (2013); Innovation Act, H.R. 9, 114th Cong. (2015).

131. *Promoting the Useful Arts: How Can Congress Prevent the Issuance of Poor Quality Patents?: Hearing Before the Subcomm. on Intell. Prop. of the S. Comm. on the Judiciary*, 116th Cong. (2019), https://www.judiciary.senate.gov/meetings/promoting-the-useful-arts-how-can-congress-prevent-the-issuance-of-poor-quality-patents [https://perma.cc/C7P2-VKY4].

is in fact wrong. Broadly, this can lead to two types of errors: erroneous rejection of a patent application (when a prior art disclosure of the applicant's invention is incorrect) or erroneous grant of a patent application (when the applicant's evidence about the invention is incorrect). These two types of errors are discussed in Parts II.B.2.a and II.B.2.b, respectively.

In theory, digging errors could also occur if the examiner overdigs—i.e., believes that information is wrong but the information is in fact right. This Article does not grapple with this sort of error because, given that patent examiners rarely inquire into the quality of evidence during examination,[132] it will not occur often in practice. That is, patent examiners will not generally find that a statement is wrong if it is in fact right because they do not usually make rejections on the basis that a statement is wrong.[133] However, it is worth noting that if patent procedures were reformed so that examiners dug into the quality of evidence, this type of error would become more common.

1. Information Available to Examiners Is Often Incorrect

Examiner failure to dig into information quality only matters if that information is sometimes wrong. As discussed here, there is substantial reason to believe that much evidence reviewed by patent examiners is incorrect.

When examiners review the utility, enablement, and written description requirements, they use information in the patent application's specification. This information is provided by the applicant and is often unreliable. For one, applicants are permitted by patent law to include fictional experiments in applications, and examiners routinely accept these experiments as evidence of patentability.[134] For example, an examiner granted a patent directed to a compound called *Aristolochia paucinervis* Pomel, at least in part on the basis of the following fictional reports from the patent applicant:

> A 67-year-old male has pancreatic cancer. Although he receives chemotherapy and radiotherapy, six months later his therapy is discontinued because metastases are detected. He is provided with *A. paucinervis* pomel extract for three years. The patient is examined later, and has normal renal hepatic and pulmonary test results. His tumor is reduced in mass.
>
> . . . A 58-year-old patient's history, hospitalized for icterus resulting from alcoholic hepatitis, is followed. This patient receives one-half teaspoon of *A. paucinervis* pomel extract for 40 days, stops taking the extract for 10 days, and then resumes taking the extract for an additional 40 days. The patient reports no side effects of any sort for three years following this

132. *See supra* Part I.C.
133. *See supra* Part I.D.
134. Janet Freilich, *Prophetic Patents*, 53 U.C. DAVIS L. REV. 663, 673 (2019).

> regimen. His transaminase level is normal, and no nephrotoxicity is observed in this patient.[135]

Although the examiner was aware that the studies above were fictional (studies written in the present tense are assumed to be hypothetical),[136] the examiner required no further evidence that the compound was useful.[137]

My previous work has shown that 24 percent of life sciences and chemistry patents include fictional experiments.[138] While fictional experiments are not necessarily incorrect, they are surely less likely to be correct than factual experiments.[139] If examiners routinely accept fictional experiments as evidence of an invention's utility and to meet the enablement and written description requirements, some of the examiner's decisions will be mistaken.

Even factual experiments in patent applications frequently have characteristics suggesting that they will not be replicable, such as small sample sizes, no statistical analysis, and failure to blind the investigators or randomize the subjects.[140] The experiment below, for example, is taken from a patent claiming that Bag Balm (an ointment normally used on cow udders) can, when rubbed on the head, cause hair growth[141]:

> Subject, a hair dresser in his thirties, had tried many different products on his scalp before he began using BAG BALM. He reports that BAG BALM is the best product he has ever used. After about two (2) months of daily massaging of BAG BALM into his scalp, the bald spot on top of his head was filling-in some.[142]

While I do not know whether or not Bag Balm would indeed have this effect, the replicability literature suggests that studies without controls, on only one subject and with few details about how the application was

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135. U.S. Patent No. 8,003,137 exs. 15–16 (filed May 9, 2008) (issued Aug. 23, 2011). Doctors are skeptical that the compound would produce this effect if it were actually given to humans (and, in addition, the compound is highly toxic). *See* Freilich, *supra* note 134, at 666.

136. *See* MPEP § 608.01(p) (9th ed. Rev. 10, June 2020).

137. *See id.* § 2164.

138. *See* Freilich, *supra* note 134, at 668 (explaining that applicants are incentivized to include hypotheses (in the form of fictional experiments) in patents); Freilich & Larrimore Ouellette, *supra* note 121, at 1036.

139. *See* Freilich, *supra* note 134, at 702.

140. *See* Freilich, *supra* note 50, at 432 (explaining that the patent system is set up to encourage disclosure of early-stage data that is often incorrect and documenting that most preclinical experiments in life sciences patents bear hallmarks of irreplicability); Lisa Larrimore Ouellette, *Who Reads Patents?*, 35 NATURE BIOTECH. 421 fig.4 (2017) (surveying researchers regarding the likelihood that they could replicate an invention described in a patent in their field and finding that fewer than half believed they could); Jacob S. Sherkow, *Patent Law's Reproducibility Paradox*, 66 DUKE L.J. 845, 845 (2017) (providing several examples of irreplicable disclosures in patents).

141. The examiner was skeptical of this example and rejected the patent for lack of utility. *In re* Cortright, 165 F.3d 1353, 1355 (Fed. Cir. 1999). However, the Federal Circuit reversed, explaining that examiners "cannot make this type of rejection, however, unless [they have] reason to doubt the objective truth of the statements contained in" the application. *Id*. at 1357. The court explained that this occurs when the patent "suggest[s] an inherently unbelievable undertaking," which the above experiment does not because treatments for baldness do exist. *Id.* (quoting *In re* Brana, 51 F.3d 1560, 1566 (Fed. Cir. 1995)).

142. U.S. Patent No. 6,033,676 ex. 2 (filed Mar. 11, 1992) (issued Mar. 7, 2000).

conducted, are often not replicable.[143] As with fictional experiments, if examiners regularly accept poor quality experiments as evidence of patentability, examiners' decisions as to patentability may be erroneous.

Further, if examiners never dig into the veracity of information in the patent, there is little incentive for applicants to ensure that the information in their applications is correct. Applicants may therefore include speculative statements and preliminary experiments without being cautious about the accuracy of the information. This suggests that the patent system has the practical effect of incentivizing inclusion of inaccurate statements in patent applications.

With respect to examination for novelty and nonobviousness, examiners review evidence in the prior art.[144] The prior art consists of the entire canon of publicly available information—and anyone who has spent time on the internet knows that much publicly available information is incorrect. Further, examiners predominantly search for prior art in the patent literature, meaning that they are searching for documents that suffer from the flaws described above.[145]

2. Types of Errors

Given that much information available to examiners is incorrect and that examiners do not dig into the quality of that information, errors will occur. Relying on incorrect information during examination can lead both to erroneous grants and erroneous rejections of patent applications. If the incorrect information is in the prior art, examiners will erroneously believe that the patent application is anticipated or obvious and will wrongly reject the application. If the incorrect information is in the specification, examiners will erroneously believe that the applicant has satisfied the utility, enablement, and/or written description requirements and will wrongly grant the patent application.

These two types of errors have fundamentally different sources and solutions. Incorrect statements in the specification are the fault of the applicant[146] and are also known to (or should be known to) the applicant. Incorrect statements in the prior art arise from external sources.[147] This distinction impacts the policy tools available to address the errors, as discussed further below.

a. Erroneous Rejection

Failure to dig into the quality of information used during examination causes erroneous rejection when a patent application that should have been granted is denied because it is rejected as either anticipated or obvious.

143. Freilich, *supra* note 50, at 449.
144. 35 U.S.C. §§ 102–103.
145. Chien, *supra* note 88, at 112–13.
146. Whether or not the statements are deliberately incorrect.
147. On occasion, prior art may be the applicant's own previous public statements.

However, the rejection is incorrect because the alleged disclosure in the prior art in wrong.

The following is an example of an erroneous rejection. In 2013, researchers at Harvard University found that a compound called betatrophin could stimulate the growth of pancreatic β-cells, which are responsible for insulin production, and therefore might treat or even cure diabetes.[148] Unfortunately, the discovery was wrong. The authors retracted the paper and stated that "the betatrophin hypothesis needs to be withdrawn."[149] In 2015, a separate research team from Scripps's California Institute of Biomedical Research filed a patent application on a method of combining betatrophin with antibody regions known to enhance binding activity.[150] The Scripps team claimed that these fusion proteins could be used to treat diabetes.[151] In a series of rejections beginning in June 2017 (one year after the Harvard team had publicly acknowledged that its findings were incorrect), the examiner rejected the Scripps team's application because, among other reasons, it was obvious over the Harvard team's work.[152]

The examiner stated repeatedly that the Scripps team's use of a fused betatrophin-antibody protein to treat diabetes was obvious because the Harvard team "teaches a composition comprising betatrophin and an antibody that is used to treat diabetes."[153] However, the examiner's statement about the teaching of the Harvard study is wrong, as evidenced by the subsequent retraction of the Harvard paper.[154] Eventually, the Scripps team amended its claims to considerably narrow the scope of its application, losing patent scope at least in part because the examiner believed that the Harvard team's research was correct. It is possible that, while the Harvard team could not use betatrophin to treat diabetes, the Scripps variation *could*

148. Peng Yi et al., *Betatrophin: A Hormone that Controls Pancreatic β Cell Proliferation*, 153 CELL 747, 747 (2013).

149. Aaron R. Cox et al., *Resolving Discrepant Findings on ANGPTL8 in β-Cell Proliferation: A Collaborative Approach to Resolving the Betatrophin Controversy*, PLOS ONE 17 (July 13, 2016), https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0159276 [https://perma.cc/84UF-XZRQ]; *see also* Peng Yi et al., *Retraction Notice to: Betatrophin: A Hormone that Controls Pancreatic β Cell Proliferation*, 168 CELL 326, 326 (2017) ("[W]e claimed that . . . betatrophin . . . induces robust β-cell replication in mice. . . . When we repeated our original experiments with a larger number of mice, we also failed to observe β-cell expansion . . . . [We] have now determined conclusively that our conclusion that . . . betatrophin causes specific β-cell replication is wrong and cannot be supported.").

150. U.S. Patent No. 10,259,863 cols. 1–2 (filed Jan. 10, 2014) (issued Apr. 16, 2019).

151. *Id.* col. 7.

152. *E.g.*, Final Rejection 3 (U.S. Patent No. 10,259,863) (filed June 22, 2017).

153. *Id.*

154. Note that prior art used in an obviousness rejection does not have to be enabled (that is, it does not have to work). MPEP § 2121.01 (9th ed. Rev. 10, June 2020). However, obviousness rejections can be overcome by demonstrating that the prior art teaches away from the applicant's invention, and a retraction notice that suggests that betatrophin does not treat diabetes certainly teaches away from using betatrophin to treat diabetes. *See In re* Gurley, 27 F.3d 551, 553 (Fed. Cir. 1994) ("A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant.").

do so. If that is the case, the patent system may be insufficiently incentivizing the second patent applicant in situations where the earlier patent or application contains unreliable evidence.

Erroneous rejections of this sort could result in systematic undervaluing of second-comers' research in fields where the first innovator's research was speculative or outright wrong. This may disincentivize such research because patents on second-comers' research would either not be granted at all or would be narrower than expected.[155] If innovators believe that they will not be adequately rewarded for their work, they may be deterred from innovation even before any encounter with the PTO.[156] Thus, erroneous denials of patents may hamper incentives to innovate.

However, erroneous rejections are not overly concerning because, though potentially serious if allowed to stand, they are readily fixable by the applicant. In situations where an examiner has rejected an application using prior art that contains some suspect statement, the applicant can—and has every incentive to—dig into the evidence themselves. The applicant can identify the problem with the prior art statement, tell the examiner that the prior art is wrong, and ask the examiner to withdraw the rejection.[157] This was not done for the betatrophin patent discussed above (for unknown reasons)[158] but patent applicants have done this successfully in other cases. For example, during prosecution of the patent covering an osteoporosis drug Evista, the applicants overcame an erroneous rejection by telling the examiner that the prior art contained errors;[159] they were granted the patent and made several billion dollars in selling the drug.[160] Digging errors that lead to erroneous rejections might be common and potentially harmful, but they can also be quickly fixed.

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155. Andres Sawicki, *Better Mistakes in Patent Law*, 39 FLA. ST. U. L. REV. 735, 761–62 (2012); Stephen Yelderman, *The Value of Accuracy in the Patent System*, 84 U. CHI. L. REV. 1217, 1220 (2017).

156. Yelderman, *supra* note 155, at 1220.

157. 37 C.F.R. § 1.111(b) (2020).

158. Perhaps the applicants were unaware of the retraction. The scientists on the Scripps team presumably knew that Yi and Melton's work had failed because it was a high-profile retraction. *E.g.*, Damien Garde, *Once-Promising Diabetes Breakthrough Isn't After All Scientist Says*, BOS. GLOBE (Dec. 27, 2016, 7:38 PM), https://www.bostonglobe.com/metro/2016/12/27/diabetes-breakthrough-isn-after-all-scientist-says/4u4ljoUA1WgmupriqnOkYP/story.html [https://perma.cc/2YYK-W35S]. However, the communications between the examiner and the applicant are generally written by attorneys, perhaps in consultation with a technology transfer office when, as here, the applicant is based out of a university. The scientists themselves are not always consulted, which may explain the lack of response in this case.

159. Eli Lilly & Co. v. Teva Pharms. USA, Inc., 657 F. Supp. 2d 967, 988 (S.D. Ind. 2009). The patent was originally rejected by the examiner as anticipated by an article that disclosed use of raloxifene to treat osteoporosis. *Id.* The applicant submitted a declaration explaining certain flaws in the article that rendered it unreliable, after which the examiner granted the patent. *Id.*

160. *Ten Blockbuster Drugs That Lost Patent in 2014*, CLINICAL TRIALS ARENA (Nov. 20, 2014, 6:30 PM), https://www.clinicaltrialsarena.com/features/featureten-blockbuster-drugs-that-lost-patent-in-2014-4445799/ [https://perma.cc/XF7T-SNL5].

b. Erroneous Grant

Errors in evaluating information quality that lead to erroneous grants are also common and potentially harmful but, unlike erroneous rejections, are difficult to fix. An erroneous grant due to a digging mistake occurs when an examiner grants a patent that is in fact not useful, not enabled, or not adequately described. In this type of error, an examiner will find that the patent application contains statements of utility, teachings of how to make and use the invention, and explanations showing possession, but these statements are not correct—which will not be discovered by the examiner because the examiner did not evaluate the reliability of the evidence.

Unlike erroneous rejections, this type of error is unlikely to be fixed during prosecution. There are two parties involved in patent prosecution: the examiner and the applicant. The examiner will not fix these digging errors because the examiner (having already made the error) evidently holds erroneous beliefs about the evidence under examination. The applicant will not fix the error because there is no incentive for applicants to correct mistakes that cause their applications to be granted.

These mistakes are harmful. An erroneously granted patent gives its owner the exclusive right to make and use the invention where such a right is not warranted.[161] These patents disincentivize inventors other than the patentee from working in the field covered by the patent because third parties must obtain a license from the patentee. When a patent is erroneously granted due to a digging error—when the patentee does not actually know how to make and use the invention or is unaware of its utility—patent grant precludes others from discovering the invention's use or how it works. Since the inventor does not know how to make the invention and others are blocked from finding out, this has the practical effect of preventing anyone from making or using the invention. If Jules Verne had been granted a patent on a submarine[162] (which he imagined in his writing but could not actually make), he could have used the patent to block others who were trying to truly develop the technology and we might not have submarines. Because Theranos was granted dozens of patents on diagnostic technology, these patents can be asserted against other innovators—even though Theranos could not make its technology work and other innovators appear to have working technology.

Patents granted erroneously due to digging errors are a particular problem because they are often broad in scope and may cover—and block others from discovering—downstream uses that the patentee never thought of.[163] The impact of erroneously granted patents is particularly acute in the United States because there are few exceptions to patent infringement.[164] There are

161. 35 U.S.C. § 271(a).

162. *See generally* JULES VERNE, TWENTY THOUSAND LEAGUES UNDER THE SEA (Chicago, Butler Bros. 1887).

163. *See* Freilich, *supra* note 134, at 688.

164. 35 U.S.C. § 271(a) (allowing patent owners to prevent others from making, using, selling, offering for sale, or importing their inventions).

no exceptions for independent invention,[165] research that improves on a technology,[166] socially desirable "fair use,"[167] or use of a technology for public health or to save a life.[168] Thus, the consequences of erroneous patent grants are severe.

Finally, erroneous grants create harm because they publicize documents with incorrect information. One purpose of patents is to publicly disclose information about new technologies that can then be used by others to build on and further develop the science.[169] However, if the information in patents is wrong, the disclosure function of patents works poorly.[170]

C. Benefits of the Status Quo

Examiner failure to dig into the quality of evidence during examination creates serious costs in the form of erroneously granted patents. However, the current system—where examiners match but do not dig—has certain advantages.

The first benefit of the status quo is the cost of examination. Digging takes time and resources and is consequently expensive. Asking examiners to verify evidence to prevent errors would be costly, and the cost may outweigh the expense of the errors themselves.[171] Thus, a system where examiners

165. Several scholars have argued that there should be such an exception. *See, e.g.*, Mark A. Lemley, *Should Patent Infringement Require Proof of Copying?*, 105 MICH. L. REV. 1525, 1526 (2007); Samson Vermont, *Independent Invention as a Defense to Patent Infringement*, 105 MICH. L. REV. 475, 476 (2006).

166. Although, under the reverse doctrine of equivalents, a device that literally falls within the claims of a patent may not infringe if it "has so far changed the principle of the device that the claims of the patent, literally construed, have ceased to represent" the device. Westinghouse v. Boyden Power Brake Co., 170 U.S. 537, 568 (1898). However, the reverse doctrine of equivalents is functionally dead, as the Federal Circuit has never used it and has called the doctrine an "anachronistic exception, long mentioned but rarely applied." Tate Access Floors v. Interface Architectural Res., Inc., 279 F.3d 1357, 1368 (Fed. Cir. 2002) ("Not once has this court affirmed a decision finding noninfringement based on the reverse doctrine of equivalents.").

167. Such an exception exists for copyrights. *See* 17 U.S.C. § 107. The statute excludes from infringement "fair use" of a copyrighted work, such as use for "criticism, comment, news reporting, teaching . . . scholarship, or research" and provides four factors to guide analysis of whether an action constitutes fair use. *Id.* Scholars have argued that there should be a fair use doctrine in patent. *See* Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177, 1178 (2000).

168. Under the Bayh-Dole Act, Pub. L. No. 96-517, 94 Stat. 3015 (1980) (codified as amended in scattered sections of the U.S.C.), the government has "march-in rights" to patents funded by federal agencies and can require the patentee to grant a license to the patented technology if "action is necessary to alleviate health or safety needs." 35 U.S.C. § 203(a)(2). However, these rights are somewhat illusory as they have never been used.

169. *See, e.g.*, Graham v. John Deere Co. of Kan. City, 383 U.S. 1, 6 (1966) ("[T]hings which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of . . . useful Arts.'" (alteration in original) (quoting U.S. CONST. art I, § 8, cl. 8)).

170. *See, e.g.*, W. Nicholson Price II, *Regulating Secrecy*, 91 WASH. L. REV. 1769, 1805 (2016) ("[D]isclosure is undoubtedly a key component of cumulative innovation . . . .").

171. *Compare* Lemley, *supra* note 124, at 1495, *with* Michael Frakes & Melissa Wasserman, *Irrational Ignorance at the Patent Office*, 72 VAND. L. REV. 975, 976 (2019).

search for, but do not evaluate the quality of evidence, is substantially cheaper and faster than the alternative.

A second benefit of a system where examiners only conduct a matching analysis is the consistency and standardizability of examination. There are thousands of patent examiners.[172] Ideally, the outcome of prosecution should not depend on the individual examiner to which the patent is assigned.[173] Thus, each examiner should follow a set of processes that can be standardized across the PTO and that would result in similar outcomes if followed by a different examiner. This goal is easier to achieve for matching than for digging because matching is more objective. If one were to search a database for a particular technology and get a specific result, someone else searching in the same database for the same technology should be able to obtain similar findings.[174] The precise outcome will of course differ based on choices such as search terms but, on the whole, the process ought to be at least somewhat replicable.

By contrast, digging into the veracity of evidence is considerably harder to standardize. How would examiners know when to accept a statement as true or when to dig further? If digging further, what sources should be consulted? When is a source sufficiently reliable to corroborate a statement? Protocols can certainly be developed to standardize this process, but there is more subjective judgment involved for digging than for matching, so consistency in digging is harder to achieve.

For similar reasons, it is easier to document, explain, and challenge matching decisions than digging decisions. Examiners record search strategies[175] and then write a letter to the applicant stating any matches found between the application's claims and the prior art.[176] For example, in a sample patent application claiming "extruding a chlorinated polymer" at an angle of 30 degrees, the examiner wrote that a prior art reference by Berridge taught an extruding chlorinated polymer and a prior art reference by McGee taught extrusions of 25–35 degrees.[177] Thus, it is well documented that each

172. Frakes & Wasserman, *supra* note 171, at 613.

173. Although there is substantial evidence that it does. *See, e.g.*, Mark A. Lemley & Bhaven Sampat, *Examiner Characteristics and Patent Office Outcomes*, 94 REV. ECON. & STAT. 817, 819 (2012); Iain Cockburn et al., *Are All Patent Examiners Equal?: The Impact of Examiner Characteristics*, 24–25 (Nat'l Bureau Econ. Rsch. Working Paper No. 8980, 2002), https://www.nber.org/system/files/working_papers/w8980/w8980.pdf [https://perma.cc/C8QS-CVLT].

174. Though, efforts to standardize have created challenges for the searching process. For example, the PTO has discouraged examiners from taking "[o]fficial notice unsupported by documentary evidence," which has prevented examiners from making rejections based on common sense (which is not always found in the literature). MPEP § 2144.03 (9th ed. Rev. 10, June 2020); *see also* Jorge L. Contreras, *Common Knowledge and Non-patent Literature in the Internet Age*, BERKELEY TECH. L.J. ONLINE (Mar. 12, 2016), https://btlj.org/2016/03/common-knowledge-and-non-patent-literature-in-the-internet-age-2/ [https://perma.cc/B7X3-DS9W].

175. A full set of the examiner's searches can be found in the prosecution history of each application. MPEP § 719.05.

176. This occurs in a document called an "Office Action." MPEP § 2262.

177. *Id.*

element of the application's claim ((1) extruding chlorinated polymers, (2) at 30 degrees) is present in the prior art. The applicant can see those reasons, review the prior art for herself, and respond to the examiner's rejection if she believes that the match is incorrect. Conversely, because digging is more subjective, examiner decisions about the reliability of evidence would be harder to explain and consequently harder to challenge.

Finally, in certain circumstances, it is appropriate to put the burden of digging on the applicant. In the context of erroneous rejections, the current system correctly places the burden of digging on the applicant. Erroneous rejections occur when the examiner rejects an application over prior art, but there is some flaw in the prior art such that it does not actually anticipate or render obvious the invention.[178] In the case of an erroneous rejection, the applicant has an opportunity to reply and argue against the rejection by presenting evidence to the examiner that the rejection was wrong and should be withdrawn.[179] Between the examiner and the applicant, the applicant is better positioned to uncover flaws in the prior art because the applicant is more likely to be an expert in the field.[180] Thus, the current system sensibly puts the burden of digging on the applicant.

III. FURTHER IMPLICATIONS AND REFORM

Understanding patent examination as a process dedicated to finding, but not evaluating, information suggests a new category of examiner errors. It also provides further insight into patent theory and avenues for reform. Part III explores additional implications and presents several specific policy recommendations. Part III.A explains that current methods of fixing errors in the patent system will not solve digging errors because, unlike matching errors, digging errors are characterized by asymmetric access to information. This is followed by proposals for information-forcing mechanisms to remedy the asymmetry and fix digging errors. Part III.B frames prosecution and litigation as procedures that do fundamentally different things: matching occurs during prosecution; digging during litigation. It therefore follows that litigation should not wholesale copy doctrines of patentability from prosecution—and several doctrines are identified as ripe for change. Part III.C argues that, since patent examination is a series of matching steps, it is particularly amenable to automation.

178. *See supra* Part II.C.1.

179. 37 C.F.R. § 1.111 (2020) ("If the Office action . . . is adverse in any respect, the applicant or patent owner . . . must reply and request reconsideration . . . .").

180. The examiner has a general background in the field, but the applicant works in the specific field of the invention. *See Become a Patent Examiner*, U.S. PAT. & TRADEMARK OFF. https://www.uspto.gov/jobs/become-patent-examiner [https://perma.cc/6PL4-MBDX] (last visited Mar. 16, 2021) (click "Qualifications" under "I'm interested! Tell me more . . . ") ("Minimum of a bachelor's degree in engineering or science.").

A. Fixing Errors

Part II argued that erroneous grants of patents due to digging errors are common and harmful. This section explores how these errors can be addressed. At the outset, any type of error—matching or digging—can be corrected in litigation, where a court can review the examiner's grant of the patent and can find the patent invalid.[181] However, litigation is expensive. Further, a challenger trying to prove that a patent is invalid is at an initial disadvantage in litigation because granted patents are presumed to be valid.[182] Downstream researchers may therefore choose to avoid litigation and either pay for a license based on an erroneously granted patent or simply shift their research to a different area.[183] So-called "patent trolls" leverage the difficulty of litigation to extract rents from baseless patent claims.[184]

Efforts at fixing erroneously granted patents have therefore focused on prevention and on quick fixes that avoid the need for lengthy and expensive litigation.[185] Because there is a large existing scholarship on errors during examination, there is also an extensive array of policy proposals to prevent or fix such errors, some of which have been enacted by Congress.[186] However, like the existing scholarship on examination errors, existing policy proposals relating to fixing those errors are focused predominantly on matching errors—examiner failure to find relevant information.[187] But there is a critical difference between matching errors and digging errors: matching errors are equally visible to both the applicant and to others, such as the examiner and the public; digging errors are often not. Unfortunately, most existing mechanisms to address erroneously granted patents require the error to be visible to either the examiner or to third parties and therefore, will not be as effective at finding or fixing digging errors.

The following section begins by explaining that, because digging errors—unlike matching errors—are characterized by information asymmetry, existing policy mechanisms will not be effective. I then propose a new set of policies to address the particular problems caused by failure to dig into information quality.

1. Information Asymmetry

When an inventor writes a statement in a patent application, such as "widgets inhibit the growth of cancer cells," the applicant knows how much and what type of evidence supports that statement. The public does not, nor do patent examiners. The statement might be backed up by extensive clinical

181. 35 U.S.C. § 282(b)(1).
182. *Id.* § 282(a).
183. *See, e.g.*, Lichtman & Lemley, *supra* note 122, at 48.
184. *E.g.*, BESSEN & MEURER, *supra* note 122, at 3; John M. Golden, *"Patent Trolls" and Patent Remedies*, 85 TEX. L. REV. 2111, 2128 (2007).
185. *See, e.g.*, Paul R. Gugliuzza, *Quick Decisions in Patent Cases*, 106 GEO. L.J. 619, 619 (2018).
186. Most notably, the creation of inter partes review proceedings. 35 U.S.C. § 311.
187. *See infra* notes 192–97 and accompanying text.

trials and be highly reliable, or it might be entirely speculative and founded simply on conjecture. The applicant does not need to disclose how much or what type of evidence supports statements in the patent application, so examiners and the public have no easy way to flag statements that are likely to be wrong.

This is well illustrated by the long fraud perpetuated by Theranos. The company claimed that it was able to make diagnoses based on small drops of blood.[188] The public had no access to the data underlying that claim and was therefore unable, at least for a time, to suspect that Theranos's technology did not work.[189]

Further, third parties cannot simply test the applicant's statement, because doing so would likely be patent infringement.[190] Further, there are a host of other practical difficulties involved in investigating the veracity of a claim in a patent, including the cost of replication trials, the ability to repeat an experiment if very few details are given about experimental conditions, and, for life sciences patents, ethical concerns.[191] It is therefore often not possible for third parties to obtain information about the quality of a statement in a patent application.

While the process of digging into information quality is characterized by asymmetrical access to information, the process of matching information is equally available to the applicant, the examiner, and the public. For example, if a patent application claims widgets, an examiner will search the prior art for information on widgets. Perhaps the examiner will overlook a piece of matching information in the prior art and erroneously grant the patent. The prior art is, by definition, public, so third parties can conduct their own searches and find the overlooked information.[192] Applicants, examiners, and third parties all have access to the same prior art.[193]

Current policy mechanisms, built with matching errors in mind, rely on the ability of examiners or third parties to find errors. Because this is possible

188. Press Release, U.S. Dep't of Justice, *supra* note 5.

189. *Id.*

190. Using a patented invention is infringement. 35 U.S.C. § 271. However, some dicta suggests that there may be an exception for testing the patented invention. Whittemore v. Cutter, 29 F. Cas 1120, 1121 (C.C.D. Mass. 1813) (No. 17,600) ("[I]t could never have been the intention of the legislature to punish a man, who constructed [a patented] machine . . . for the purpose of ascertaining the sufficiency of the machine to produce its described effects."). This passage is quoted as the origin of the experimental use doctrine, which has been essentially eliminated in recent years. *See, e.g.*, Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002); Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343, 1349 (Fed. Cir. 2000).

191. For example, if a patentee claims that widgets treat cancer but a third party is skeptical that this is true, it is not ethical to run a clinical trial testing whether widgets in fact treat cancer.

192. *See* 35 U.S.C. § 102(a)(1) (listing disclosures that qualify as prior art). On rare occasions, prior art will not be public for a time (specifically patent applications that have not yet been published, *id.* § 102(a)(2)), but these disclosures will become public after a short period. *Id.* § 122(b). Patent specifications, where examiners search for information relating to utility, enablement, and written description, are also public with minor exceptions for national security purposes. *Id.* § 181.

193. Matching might be somewhat easier for the applicants, because they are presumably familiar with the literature in their fields of study, but third parties can, with time and effort, catch up.

for matching errors but considerably harder for digging errors, these mechanisms may not work in the context of digging errors. This section discusses two popular approaches for addressing errors.

One widespread proposal for alleviating examination errors is to give patent examiners more time to review each application.[194] The intuition is that many mistakes occur because examiners are rushed; therefore, if examiners could devote additional effort to reviewing applications, they would make fewer mistakes. This is likely true for matching errors—the universe of prior art is exceedingly large and examiners currently have approximately twenty hours to handle all aspects of examination for each application.[195] Empirical work has shown that increasing the amount of time available to examiners reduces the number of errors.[196] But increasing the amount of time available to examiners will not substantially reduce the number of digging errors.[197] The problem with digging is not that examiners lack time, it is that they lack information. Thus, this proposed mechanism addresses only matching errors.

A second mechanism to address examiner errors is inter partes review (IPR) proceedings. IPR proceedings allow third parties, even those who would not have standing to challenge a patent in court, to petition the PTO to review the patent.[198] IPR proceedings are required to finish on a timeline much shorter than that of a court case and are considerably cheaper, in part because they permit only limited discovery.[199] The proceedings were authorized by Congress as part of the 2011 Leahy-Smith America Invents Act[200] in recognition of the need for cheaper, faster, and more available patent challenges.[201] IPR proceedings are designed to catch examiner errors and remove those patents without the need for litigation.

However, IPR proceedings will only fix matching errors. At present, IPR proceedings can only be brought on the grounds that a granted patent is not novel or is obvious.[202] Granted patents that are in fact not novel or are

194. Michael D. Frakes & Melissa F. Wasserman, *Is the Time Allocated to Review Patent Applications Inducing Examiners to Grant Invalid Patents?: Evidence from Micro-level Application Data*, 99 REV. ECON. & STAT. 550, 560 (2017); Sean B. Seymore, *The Presumption of Patentability*, 97 MINN. L. REV. 990, 995 (2013); John R. Thomas, *Collusion and Collective Action in the Patent System: A Proposal for Patent Bounties*, 2001 U. ILL. L. REV. 305, 314.

195. Frakes & Wasserman, *supra* note 194, at 550.

196. *Id.*

197. Of course, if examiners had unlimited time to review patent applications, they could attempt to replicate studies and test the veracity of statements in patent applications. But the time required would be considerable.

198. 35 U.S.C. § 311(a).

199. COLIN G. SANDERCOCK & TODD R. SAMELMAN, PERKINS COIE LLP, AIPLA 2012 ANNUAL MEETING: DISCOVERY PROCEDURES UNDER THE AIA 2 (2012), https://www.perkinscoie.com/images/content/2/7/v2/27610/12-10-sandercock-samelman-discoveryprocedures.pdf [https://perma.cc/SV54-RU9Q].

200. Pub. L. No. 112-29, 125 Stat. 284 (2011) (codified in scattered sections of the U.S.C.).

201. Stephen Yelderman, *Prior Art in Inter Partes Review*, 104 IOWA L. REV. 2705, 2706 (2019).

202. 35 U.S.C. § 311(b). The proceedings are also restricted to prior art patents or printed publications. *Id.*

obvious are the result of matching errors where the examiner failed to find relevant prior art. Thus, digging errors cannot be addressed through IPR proceedings as they are currently conceived. However, even if the proceedings were reformed to allow challenges on the grounds that the patented invention is not useful, enabled, or adequately described (grounds that result from digging errors), it would be difficult for the proceedings to address these errors effectively because the proceedings rely on the public to identify errors and bring a challenge but do not have the same discovery mechanisms as litigation.[203]

2. Information-Forcing Mechanisms

The solution, put broadly, is to imbue the patent system with information-forcing mechanisms that require or incentivize patentees to provide additional information about the quality of evidence supporting statements in the patent specification. This effectively outsources the task of digging into information quality from examiners to applicants. It does not perfectly substitute for a process by which examiners independently verify information in the patent, but it can approximate some features of that process.

Information-forcing mechanisms can improve the patent system during prosecution or after patent grant. During prosecution, additional information can improve examiners' ability to dig into the reliability of applicants' statements in the specification. If provided after patent grant, additional information can help third parties identify erroneously granted patents. The sections below set out several potential information-forcing mechanisms, but these are not exclusive: the principle can be applied in many ways.

a. During Examination

A key element of the information-forcing mechanisms set out below is that they put the burden on the applicant to provide additional support for statements in the prosecution, rather than asking examiners to do further digging into the quality of evidence. This is because examiners are not well positioned for this task. First, applicants have more access to information about the reliability of evidence than examiners. Second, it would be enormously expensive and time-consuming[204] to ask examiners to assess the reliability of statements in applications or prior art, particularly because doing so might require building lab facilities and replicating experiments that cost many thousands of dollars. Moreover, examiners do not have the expertise. Examiners have at least a bachelor's degree in the subject that they

203. Note that postgrant review does allow arguments about utility, enablement, and written description. *Id.* § 321(b). However, these proceedings are rarely used. Colleen Chien et al., *Inter Partes Review and the Design of Post-grant Patent Review*, 33 BERKELEY TECH. L.J. 817, 827 (2018).

204. Examiners are already short on time, which is thought to underlie the large number of patents granted despite being obvious or anticipated. *E.g.*, Frakes & Wasserman, *supra* note 194, at 551.

are examining,[205] but this does not mean that an examiner would have the ability to conduct replication experiments or even to carefully dig into data and results as a peer reviewer would do.[206] Finally, the cost-benefit analysis is unclear: the expense of carefully digging into data might be higher than the expense of patent errors.[207]

Instead of requiring examiners to further dig into the quality of evidence in patent applications, the system should ask applicants to provide additional support for their statements. This takes advantage of applicants' superior knowledge. Examiners would then take the additional evidence and match it to statements in the specification. By using matching to capture some of the benefits of digging, these policy reforms fit better with examiners' expertise and capability and are less expensive and time-consuming.

One approach would require applicants to submit corroborating evidence for statements made in the patent specification. Examiners would then match statements in the patent application to the additional evidence. If statements in the application are corroborated by the additional evidence, the statements are more likely to be correct. For example, for each step required to make a product, the applicant could submit either documentation from the prior art on how that step was conducted or, if the step was novel, lab notebooks documenting performance of the step and the outcome.[208] Alternatively, the examiner could ask for a physical model of the invention and ensure that each element claimed by the patent matched an element in the physical model.[209] Where images in the patent are used to corroborate applicant claims, examiners should require that applicants furnish new drawings if the submitted drawings are unreadable.[210] For inventions not physically reduced to practice, examiners could ask for extensive documentation explaining why each novel step would be expected to work.[211]

This would be very roughly akin to the practice of footnoting a law review article—the article makes a novel argument but footnotes each step needed to support the argument so that the reader can be confident that the novel portion of the article is plausible. Law review editors, like patent examiners, cannot fully verify the reliability of each statement in a law review article.

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205. U.S. PAT. & TRADEMARK OFF., *supra* note 180.

206. Ronald J. Mann, *The Idiosyncrasy of Patent Examiners: Effects of Experience and Attrition*, 92 TEX. L. REV. 2149, 2163 (2014).

207. *See supra* Part II.C.

208. This would work only for inventions physically reduced to practice.

209. Under current PTO practice, examiners only request physical models to prove operability for patents on perpetual motion machines (presumably because the applicant would not be able to create a physical model). MPEP § 608.03 (9th ed. Rev. 10, June 2020) ("With the exception of cases involving perpetual motion, a model is not ordinarily required by the Office . . . ."). However, the PTO has the power to make these requests. 35 U.S.C. § 114 ("The Director may require the applicant to furnish a model of convenient size to exhibit advantageously the several parts of his invention."). Historically, the PTO did require physical models of inventions when a patent application was filed. Christopher A. Cotropia, *Physicalism and Patent Theory*, 69 VAND. L. REV. 1543, 1547 (2016).

210. *See supra* Part III.C.3.a.

211. At present, applicants may be reluctant to provide this sort of evidence lest it make the invention appear obvious.

But they can ensure (via footnotes) that each building block of a novel argument matches a prior published statement.

Once the applicant has supplied such evidence, the examiner could ensure that each step in the patent was corroborated by additional evidence. To be sure, these changes would be complex and add additional work for the applicant and the examiner. However, the applicant ought to be in possession of much of the corroborating evidence anyway, so disclosing it to the PTO might not add a substantial burden for the applicant. Although there would be an additional burden on the examiner, it would be a smaller burden than requiring examiners to conduct their own analyses into the reliability of the evidence provided by the applicant.

The PTO could also encourage examiners to take certain actions toward digging into information quality. Examiners could search for third-party opinions about a particular technology—essentially the same matching steps that are taken in the context of novelty and nonobviousness—but look forward from the application date, rather than backwards. This is not done at present because examiners search for evidence that the applicant's invention existed before the application was filed and therefore truncate their searches at the date of the patent application.[212] However, because examiners are examining applications at least a year after the application has been filed[213] (and often five or ten years later, in the case of patent families),[214] other scientists will sometimes have commented on a technology in a filed application and these comments may make clear to examiners that statements in the patent are incorrect.[215]

For example, in 2017, Dr. Piero Anversa filed patent applications on various inventions involving cardiac stem cells.[216] In 2019, an examiner searched for prior art, truncating his search at the application's 2009 priority date.[217] Had the examiner searched *forward* from the priority date, he would have discovered that Piero Anversa's research is one of the most notorious examples of scientific fraud and that the invention claimed in the patent application—cardiac stem cells—apparently does not exist.[218] The examiner

212. More specifically, the priority date. 35 U.S.C. § 120; 37 C.F.R. § 1.78 (2020).

213. *Patents Pendency Data December 2020*, U.S. PAT. & TRADEMARK OFF., https://www.uspto.gov/dashboard/patents/pendency.html [https://perma.cc/4JRR-4P59] (last visited Mar. 16, 2021).

214. Mark A. Lemley & Kimberly A. Moore, *Ending Abuse of Patent Continuations*, 84 B.U. L. REV. 63, 65 (2004) (describing patents that spent decades in prosecution).

215. For example, in the patent on stem cells cited in note 115, *supra*, the journal *Science* had published an article stating that relevant data had been faked eight years before the patent was granted. *Supra* note 116. If the application is novel, these third-party comments will occur after the application is filed, not before (or at least not more than a year before the priority date). 35 U.S.C. § 102.

216. U.S. Patent Application No. 15/804,339 (filed Nov. 6, 2017).

217. Examiner's Search Strategy and Results (U.S. Patent Application No. 15/804,339) (filed June 4, 2019).

218. Gina Kolata, *He Promised to Restore Damaged Hearts. Harvard Says His Lab Fabricated Research*, N.Y. TIMES (Oct. 29, 2018), https://www.nytimes.com/2018/10/29/health/dr-piero-anversa-harvard-retraction.html [https://perma.cc/HL58-AMY6] (citing over thirty research articles that were retracted because of falsified or fabricated data, a ten-million-

did not make a rejection on the grounds that the invention did not work but,[219] had he searched forward from the priority date, he would certainly have discovered evidence justifying such a rejection. Thus, the examiner could have used a matching technique (searching for information in documents published after the patent's filing date) to analyze the quality of evidence in the patent and avoid an error.

To avoid undue burden on both applicant and examiner, these policies could be targeted to patent applications that are particularly susceptible to errors in information quality. Jorge Contreras has suggested that the PTO could keep a list of names appearing on retracted papers, in criminal proceedings related to fraud, and involved in securities investigations.[220] Should these individuals be named as inventors on patent applications, the PTO could apply more scrutiny. Contreras further suggests heightened scrutiny of technologies in categories that are particularly suspect, which was done historically by a now defunct PTO program.[221]

The suggestions above of methods to use matching techniques to better analyze evidence are merely illustrative. There are many other possible ways to adapt matching for evidentiary analysis. Cataloguing each is beyond the scope of this Article. Rather, this Article seeks to establish a template for examination reform: digging into evidence is difficult for examiners, but some of the goals of such scrutiny can be approximated using information provided by applicants—thus taking advantage of applicants' superior access to information.

b. Beyond the Examiner

The goal of encouraging information disclosures can be applied beyond the applicant and examiner. In some circumstances, other parties would be both motivated to elicit and capable of eliciting information about the quality and veracity of evidence in patent applications.

First, the duty of disclosure could be leveraged to encourage lawyers, assignees, and technology transfer offices (TTO) to evaluate the quality of evidence in filed patent applications. Everyone associated with patent filing—inventors, attorneys, assignees, TTOs—owes the PTO duties of disclosure, candor, and good faith.[222] Attorneys, assignees, and TTOs could be a powerful check on applicants tempted to include inaccurate or

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dollar settlement between Anversa's employer and the U.S. Department of Justice over charges of fraudulently obtaining research funding, and multiple quotes from respected scientists explaining that Anversa's work is wrong).

219. The examiner issued only one rejection, which did not discuss the invention's operability. *See* Non-Final Rejection 3–4 (U.S. Patent Application No. 15/804,339) (filed June 4, 2019).

220. *See* Jorge L. Contreras, *Patent Fakes: How Fraudulent Inventions Threaten Public Health, Innovation, and the Economy*, BILL OF HEALTH (July 1, 2020), https://blog.petrieflom.law.harvard.edu/2020/07/01/patent-fakes-fraud-inventions-covid/ [https://perma.cc/LT8L-JNAC].

221. *Id.*

222. *See* 37 C.F.R. § 1.56 (2020).

speculative statements in applications. For example, one recent Theranos patent claiming "[a] method of detecting an analyte in a . . . blood sample having a volume of less than about 500 μL"[223] (the technology widely believed to be fraudulent) was filed by attorneys at a large, very reputable intellectual property boutique.[224] The lawyers at the firm should have known—particularly by 2018, when the patent was granted—that statements coming from their client, Theranos, were suspect. The firm should have carefully reviewed the contents of the patents and asked for additional evidence. A statement from the PTO emphasizing that the duty of disclosure applies in this sort of situation could be an effective incentive for attorneys and others involved in the filing process to police information quality.

Another alternative would be to apply a higher standard of scrutiny to patent applications assigned to institutions who had previously failed to report known incorrect information to an examiner. For example, a major research university filed a patent application with a diagram that had been retracted from a paper on the same topic several years prior (as seen in Figure 1, below); applying a higher standard of scrutiny to subsequent applications from that university would incentivize the institution to carefully review its applications to avoid such accidental inclusion.

Figure 2: Retracted Image and Later Reproduction

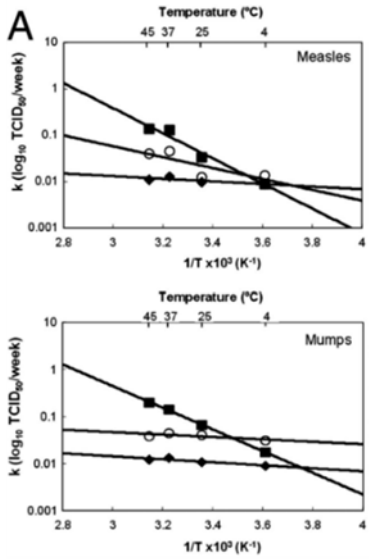


Figure 3(a) (partial)

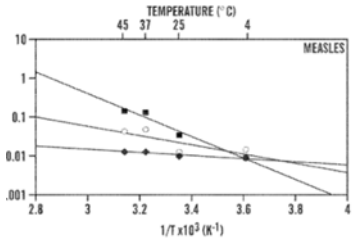
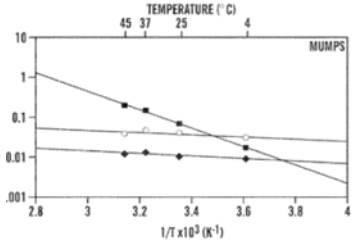


FIG. 15A



223. U.S. Patent No. 10,156,579 col. 24 (filed Feb. 26, 2016) (issued Dec. 18, 2018).
224. *See id.* at [74].

The left-hand image is a partial reproduction of figure 3(a) from a paper by Zhang et al., retracted in 2016.[225] The retraction notice specifically retracts figure 3(a), stating that the

> authors wish to note the following: "It has come to our attention that there were significant errors in the data analysis that formed the basis of Figs. 2 and 3 of this paper, and we are no longer confident in the results presented or the conclusions made from the data represented in those figures . . . ."[226]

The right-hand image is a reproduction of figure 15A from a patent filed by Tufts University (with the inventors listed as Zhang's coauthors) in 2017, which includes the retracted data.[227]

In addition, patent doctrine should be clarified to encourage third parties to test and replicate statements from the patent—providing an opportunity for others to uncover errors. A patent grant gives the patentee the right to exclude others from making and using the patented invention.[228] If a third party wanted to conduct an experiment to verify whether the information in the patent was correct, doing so would be patent infringement, and the patentee could seek an injunction or damages.[229] Although there is an experimental use exception for patent infringement, it is extremely narrow and it is not clear whether it would apply in this situation.[230] This may prevent third parties who want to investigate the veracity of a patent's statements from doing so.

Further, it impedes scrutiny by patent applicants seeking to overcome an examiner's rejection. For example, if an examiner rejects an application for lack of novelty, the applicant may wish to conduct tests to show that the prior art was not enabled and, therefore, not a valid basis for the rejection.[231] However, if the prior art is an in-force patent, the rejected applicant cannot conduct such experiments because doing so would be patent infringement. It would be helpful to have a doctrine that clearly stated that using a patented technology for purposes of determining whether a statement in the patent was correct would not constitute patent infringement.

B. Reevaluating the Prosecution-Litigation Interface

Errors are not the only implication of the matching-digging dichotomy. The framework also helps understand differences in prosecution and litigation, which in turn dictates certain policy changes. A key difference between prosecution and litigation is that examiners in prosecution do not—and often cannot—dig into the quality of evidence used to evaluate

225. Jeney Zhang et al., Retraction, *Stabilization of Vaccines and Antibiotics in Silk and Eliminating the Cold Chain*, 113 PNAS 11,981 (2016).
226. *Id*.
227. U.S. Patent Application No. 15/858,239 (filed Dec. 29, 2017).
228. 35 U.S.C. § 271(a).
229. *See id.*
230. *See* Freilich, *supra* note 50, at 473.
231. *See supra* Part II.C.

patentability. In litigation, both matching and digging occur.[232] This difference arises because prosecution is an *ex parte* proceeding with only one party (the patent applicant), whereas litigation is an adversarial *inter partes* proceeding with parties on both sides and extensive discovery proceedings. The party opposing the patent in litigation has the motivation and resources to bring arguments that would not be possible for the patent examiner.[233] In litigation, parties can and do challenge the veracity of evidence brought by the other side. This section explores how patent theory and policy should be reconceptualized and reformed to account for this difference.

1. Examination as Quasi-registration

The PTO examination process is—as the name suggests—considered an examination procedure, as opposed to a registration procedure.[234] In an examination procedure, patents are reviewed in depth by examiners with expertise in the field of the invention, an expensive and time consuming process that has the advantage of winnowing the pool of submitted applications and yielding a high-quality set of granted patents, reducing the need for later litigation.[235] In a registration process, an administrative office ensures all components needed for patentability are present but does not inspect the validity of those components at length. Registration has the advantages of being cheap, quick, and easy.[236] The public saves money by avoiding an expansive PTO staff and applicants save time, money, and effort by avoiding extended back-and-forth proceedings with the examiner. If an invalid patent were registered, it could be challenged in litigation. Registration shifts the cost of careful analysis from the prosecution stage to the litigation stage.

If patent grant is conceptualized as an event that occurs after an examination process, litigation plays a relatively smaller role in governing patent quality. However, the matching-digging dichotomy suggests a

232. This is because the veracity and reliability of a piece of evidence are often challenged by the opposing party.

233. An examiner typically has fewer than twenty hours to review each patent. Michael J. Meurer, *Patent Examination Priorities*, 51 WM. & MARY L. REV. 675, 677 (2009).

234. In its early years, the patent system functioned as a registration process. *See* Edward C. Walterscheid, *The Early Evolution of the United States Patent Law: Antecedents* (pt. 1), 76 J. PAT. & TRADEMARK OFF. SOC'Y 697, 709 (1994). The idea of moving back to a registration system is often discussed in the scholarly literature. *See, e.g.*, Roger Allan Ford, *The Patent Spiral*, 164 U. PA. L. REV. 827, 831 (2016); F. Scott Kieff, *The Case for Registering Patents and the Law and Economics of Present Patent-Obtaining Rules*, 45 B.C. L. REV. 55, 59 (2003); Lemley, *supra* note 124, at 1531; Wagner, *supra* note 120, at 2162–63. *But see* Greg Reilly, *The Complicated Relationship of Patent Examination and Invalidation*, 69 AM. U. L. REV. 1095, 1095 (2020) (arguing that the patent system presently functions as a partial registration system).

235. The current patent system is assumed to operate under an examination system. The Patent Act of 1952, 35 U.S.C. §§ 1–293, charges the PTO to "cause an examination to be made of the [patent] application." *Id.* § 131. The statute explains that such examination should determine whether "the applicant is entitled to a patent under the law." *Id.* The Act further lists requirements for patentability that must be examined. *Id.* §§ 101–103, 112.

236. *See* Merges, *supra* note 26, at 594–95.

different framing: with respect to many aspects of patent prosecution, our current system is a quasi-registration process. Examiners do not dig into or independently assess the veracity of applicants' statements and therefore, take actions more akin to registration. For example, once an examiner has found a statement in the patent that the invention is useful, she simply accepts the statement as sufficient to satisfy the utility requirement of patentability.[237] This is a registration system: the applicant must fulfill the administrative requirement of including a statement of utility; the PTO verifies that the statement is present but does not investigate further.

The import of framing patent grant as a registration event, rather than an examination event, is that many aspects of examination traditionally thought to be assessed during prosecution are in fact deferred to litigation. In this framing, courts and examiners are doing fundamentally different analyses, so courts should not defer to examiner decisions.

This is different from the status quo. At present, patents granted by the PTO are presumed to be valid and, in litigation, the challenger bears the burden of proving that the patent is invalid.[238] This assumption makes sense under an examination system, because the PTO has already done an up-front review.[239] It does not make sense under a registration system, where the PTO does a cursory assessment but relies on courts for in-depth review.

Instead of a presumption of validity, there should be a presumption of *matching*. When a court reviews the validity of a granted patent, the court would presume that the examiner matched correctly: that there are no prior art references that anticipate or render obvious the patent in suit; that, for enablement and written description, the content in the claims all appears somewhere in the specification; and for utility, that the patent contains a statement of utility. However, there would be no presumption that the evidence reviewed by the examiner is correct—that is, there would be no presumption of *digging*. The patentee would therefore bear the burden of proving that the statement of utility is correct and that the statements supporting the teachings of how to make and use the invention were also correct.

237. *See supra* Part I.C.2.

238. *See* 35 U.S.C. § 282 ("A patent shall be presumed valid."); *see also* Impax Lab'ys, Inc. v. Aventis Pharms. Inc., 468 F.3d 1366, 1378 (Fed. Cir. 2006) ("[T]he burden of establishing invalidity as to any claim of a patent rests upon the party asserting such invalidity.").

239. Though the presumption has been criticized. *See, e.g.*, John H. Barton, *Reforming the Patent System*, 287 SCI. 1933, 1934 (2000); F. Scott Kieff, *The Case for Preferring Patent-Validity Litigation over Second-Window Review and Gold-Plated Patents: When One Size Doesn't Fit All, How Two Could Do the Trick*, 157 U. PA. L. REV. 1937, 1940 (2009); Lichtman & Lemley, *supra* note 122, at 48; Sean B. Seymore, *Heightened Enablement in the Unpredictable Arts*, 56 UCLA L. REV. 127, 159–60 (2008).

2. Embrace Differences in Litigation and Prosecution

Currently, the standard for patentability is essentially the same in litigation and in prosecution.[240] However, the matching-digging dichotomy suggests that evidence is processed in very different ways during prosecution and litigation. If the PTO process looks more like registration than examination, at least with respect to some tasks, having the same standards may not make sense. Although currently many litigation doctrines mimic prosecution doctrines,[241] this should not be the case.

This section advocates for a decoupling of prosecution and litigation doctrines using the example of two specific doctrines: constructive reduction to practice and use of prophetic examples. These doctrines have been highlighted by scholars as perplexing under current patent theory. However, they are understandable (though not necessarily justifiable) if viewed as mechanisms that allow examiners to take what would otherwise be a digging task and transform it into a matching task. The doctrines accomplish this goal but in doing so require examiners to take shortcuts in processing evidence, which produces some unpleasant side effects and accounts for the doctrines' unpopularity among patent scholars. Understood this way, these doctrines are a concession to the realities of examiner abilities, but they do not achieve desirable ends in and of themselves. Therefore, they should be permitted during prosecution but viewed with more skepticism during litigation.

The doctrine of constructive reduction to practice allows patents to be granted on inventions that have never been physically created.[242] The doctrine of prophetic examples allows evidence of patentability to be provided in the form of fictional experiments.[243] These doctrines are widely unpopular with scholars and difficult to rationalize because they appear to encourage patents on technologies that do not work and incentivize disclosure of inaccurate information.[244] Further, scholars have struggled to explain the purpose behind the doctrine.[245]

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240. Although some rules, such as the standard for claim construction, are different. The standard at the PTO is the broadest reasonable interpretation, whereas courts take a narrower approach. *See, e.g.*, Jason Rantanen, "Broadest Reasonable Interpretation" and Appellate Review 7 (Aug. 3, 2016) (unpublished manuscript), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2816134 [https://perma.cc/WA7T-RRC6].

241. Some such doctrines are discussed below. *See infra* notes 242–52 and accompanying text.

242. *See* Ariad Pharms., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1352 (Fed. Cir. 2010).

243. Freilich, *supra* note 134, at 666; Freilich & Larrimore Ouellette, *supra* note 121, at 1036.

244. *See, e.g.*, Christopher A. Cotropia, *The Folly of Early Filing in Patent Law*, 61 HASTINGS L.J. 65, 67–68 (2009); Robin Feldman, *Plain Language Patents*, 17 TEX. INTELL. PROP. L.J. 289, 292 (2009); Freilich, *supra* note 134 at 687–92; Timothy R. Holbrook, *Equivalency and Patent Law's Possession Paradox*, 23 HARV. J.L. & TECH. 1, 9 (2009); Freilich & Larrimore Ouellette, *supra* note 121, at 1036; Larrimore Ouellette, *supra* note 121, at 1830; Seymore, *supra* note 239, at 131; *see also* Mark A. Lemley, *Ready for Patenting*, 96 B.U. L. REV 1171, 1178 (2016).

245. *See* 2 R. CARL MOY, MOY'S WALKER ON PATENTS § 8:93 (4th ed. 2017) (calling the doctrine of constructive reduction to practice "an attempt to provide a theoretical basis for a

Viewing these practices through the lens of the matching-digging dichotomy suggests that they exist because they permit examiners to search for evidence in the specification but do not require examiners to dig into the reliability of the evidence.

When assessing a patent application, examiners must determine whether the invention has been reduced to practice. Because reduction to practice is defined as filing a patent application on the claimed invention,[246] this is a matching analysis. The examiner need only check whether the invention is in fact described in the patent application. This means looking at the invention as defined in the claims and matching it to content in the specification.[247] Because there is no requirement that an invention be physically created, examiners need not check whether the invention actually exists, was actually made by the inventor, or actually works, thus allowing examiners to avoid an analysis that would involve digging into the reliability of the evidence. Similarly, because applicants are permitted to use prophetic examples, examiners need not ask whether data is real or whether the experiment *works* (digging tasks). Instead, they need only ask whether data is *present* (matching tasks).[248] The doctrines can therefore be explained as mechanisms to convert what would otherwise be digging tasks into matching tasks that better fit the capabilities of patent examiners.

These doctrines make some sense in the context of prosecution, as they avoid requiring examiners to conduct digging tasks that the examiners cannot do. But the standards are the same in litigation: a patent will be upheld in litigation even if it covers technology that was never physically made, and prophetic examples are permissible.[249] This may be the wrong standard. Because courts have the capacity to distinguish between inventions that are constructively reduced to practice and inventions that are physically reduced to practice, it would be reasonable to implement a standard that allows them to do so, such as a working requirement for patents[250] or a doctrine requiring

problematic practice of the PTO"); John Duffy, *Reviving the Paper Patent Doctrine*, 98 CORNELL L. REV. 1359, 1370 (2013) ("[T]he Patent Office had little or no ability to investigate the underlying physical reality of inventions.").

246. *See* Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986); Bigham v. Godtfredsen, 857 F.2d 1415, 1417 (Fed. Cir. 1988) (explaining that filing a patent application constitutes constructive reduction to practice as long as disclosure standards are met).

247. *See supra* Part III.A.

248. The PTO itself has suggested that this explanation underlies the presence of prophetic examples, though without framing the explanation in matching-digging terms: the PTO explained that clarity as to whether test results are "paper" or "working" is essential because examiners have "little or no resources to test the veracity of representations made by applicants." MPEP § 608.01(p) (4th ed. Rev. 5, Jan. 1981).

249. *See* Atlas Powder Co. v. EI Du Pont De Nemours, 750 F.2d 1569, 1577 (Fed. Cir. 1984).

250. A working requirement would mandate physical creation (or even use or manufacture) of the invention. Working requirements exist in other jurisdictions and are frequently discussed by scholars as a solution to certain problems with the patent system. *See, e.g.*, Cotropia, *supra* note 209, at 1551–53; Mayaan Perel, *From Non-practicing Entities (NPES) to Non-practiced Patents (NPPS): A Proposal for a Patent Working Requirement*, 83 U. CIN. L. REV. 747, 747–48 (2014); Ted Sichelman, *Commercializing Patents*, 62 STAN. L. REV. 341,

that, by the time of litigation, patentees must be able to substantiate the patent's statement of utility through outside evidence. It might be difficult for paper patents—patents describing products that have never been reduced to practice—to satisfy this standard.[251] However, that is a feature of the proposal, not a bug, because paper patents are precisely the sort that should be easier to challenge and harder to defend in court. Paper patents are more likely to be used by patent trolls in abusive litigation.[252]

A similar limit could apply to prophetic examples: they could be used to show enablement in prosecution but, by the time of litigation, patentees would need to show enablement using real, not fictional, evidence. Courts should not feel bound by the PTO's rule accepting certain types of evidence without scrutiny. As a general principle, because the PTO and courts evaluate evidence in starkly different ways, PTO evidentiary practices will often be inappropriate in litigation.

C. A Roadmap for Automation

The matching-digging analysis yields a final mechanism for reform: automation and artificial intelligence. Patent examiners are already stretched for time and would struggle to add additional analysis to their review of applications.[253] Adding additional patent examiners to give them more time for review would be costly. How, then, to improve patent quality without excessively increasing cost?

This Article frames most examiner work as matching tasks. This has two payoffs in the context of automation. First, computers are particularly good at matching-type tasks. Indeed, software is already involved in helping examiners match statements in the patent to statements in prior art through the use of search software.[254] If artificial intelligence could take over examiner matching tasks, human intelligence could be redeployed to more complex digging tasks. Examiner time could therefore be devoted to evaluating the evidence that artificial systems produce. Second, understanding examination as a series of matching tasks makes the process

394 (2010); Marketa Trimble, *Patent Working Requirements: Historical and Comparative Perspectives*, 6 U.C. IRVINE L. REV. 483, 483 (2016).

251. But not impossible—there may be ample prefiling evidence that the invention was useful and adequately described in the specification. For a discussion of paper patents, see UMC Elecs. Co. v. United States, 816 F.2d 647, 664–65 (Fed. Cir. 1987) (Smith, J., dissenting).

252. *See* Duffy, *supra* note 245, at 1359 (arguing that courts should revive a doctrine "which had authorized courts to discriminate against patents that were never successfully practiced by their patentees").

253. *See, e.g.*, Lauren Cohen et al., *"Troll" Check?: A Proposal for Administrative Review of Patent Litigation*, 97 B.U. L. REV. 1775, 1781 (2017) (explaining that, given the number of patent applications filed every year, "one cannot reasonably expect the USPTO to perform more than a relatively cursory examination of patents before they issue").

254. Sophisticated search systems, such as those used to find prior art, often involve artificial intelligence. For further discussion of the use of algorithms and machine learning at the PTO, see generally Arti K. Rai, *Machine Learning at the Patent Office: Lessons for Patents and Administrative Law*, 104 IOWA. L. REV. 2617 (2019).

of examination more readily adaptable to algorithmic analysis. The conceptualization introduced by this Article may guide the creation of examination software.

CONCLUSION

There are two steps to assessing evidence: matching—determining whether evidence exists—and digging—determining whether an existing piece of evidence should be believed. Patent examiners assess patentability by searching for evidence but not by digging into the reliability of evidence. Examiners therefore determine whether evidence relating to patentability exists but do not ask whether it is of good quality. Framing the examination process in this way provides insight into why several paradoxical patent doctrines exist, predicts widespread errors in the patent system, and guides policy solutions.

Beyond implications for patent scholars, lawyers, and policymakers, the matching-digging dichotomy also offers important insights for users of the patent system about what a patent actually *is*. Scientists, investors, journalists, and technology enthusiasts often point to patents as proof that an invention works. After all, the patent has been examined by an expert and certified by the government as useful and enabled.[255] Unfortunately, patent grant does not actually tell us much about whether an invention is useful or works. Viewed in light of the matching-digging dichotomy, patent grant demonstrates that the patent has been through a minimal screen and contains a threshold amount of information about how the inventor believes the invention would work. Patent grants say very little about the underlying technology.

Conceptualizing the examination process as a series of matching tasks allows sharper analysis of patent content, examination procedures, and litigation doctrines. The current practice of restricting examination to matching is not a failure but is a feature whose consequences reverberate throughout the patent system. The matching-digging dichotomy is therefore an essential tool for efforts to understand and reform the patent system.

255. Theranos investors were swayed by the company's many patents, as were potential Theranos employees; both groups believing that the patents indicated that the underlying technology was solid. *See* Daniel Nazer, *Theranos: How a Broken Patent System Sustained Its Decade-Long Deception*, ARS TECHNICA (Mar. 4, 2019), https://arstechnica.com/tech-policy/2019/03/theranos-how-a-broken-patent-system-sustained-its-decade-long-deception/ [https://perma.cc/D277-GA43].